May 16, 2008

Division of Dockets Management (HFA–305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

RE: Standards for Standardized Numerical Identifier, Validation, Track and Trace, and Authentication for Prescription Drugs (Docket No. FDA-2008-N-0120)

Foreword

The Health Industry Business Communications Council (HIBCC) has prepared the following review in response to the Food and Drug Administration’s (FDA) request for comments on Standards for Standardized Numerical Identifier, Validation, Track and Trace, and Authentication for Prescription Drugs. HIBCC is the industry’s primary ANSI-accredited Standards Development Organization (SDO) for auto-ID applications in the healthcare supply chain. As such, it represents the interests of a large constituency of medical product manufacturers and distributors.

We are providing three general observations for FDA consideration, followed by specific comments in reference to selected itemized questions posed in the FDA request. Our general observations bear directly upon our specific responses, thus providing a recommended framework for FDA consideration.

General Observations

(1) HIBCC believes that the FDA should closely examine the considerable body of standards already in place to address the identified objectives. For example, standardization for the subject matter has been resolved at the international level through the International Organisation for Standardization (ISO), through which existing standards for product identification have been in existence for quite some time. It is incumbent upon the member organizations of ISO to adopt those that are under the ISO hierarchy of standards in order to ensure that standards are globally interoperable and technical barriers to trade are avoided. It is noteworthy in this regard that the American National Standards Institute (ANSI) is a member of ISO, and is a signatory to the Technical Barriers to Trade (TBT) agreement.

(2) HIBCC has found that many commentators on this topic attribute more functions to product identification standards than are warranted. The ability to track and trace products through the medical supply chain is not dependent on the product identification standard
alone, but also on many other processes and functions where key players must work together and exchange information in a seamless manner.

In light of these essential interactions, the required aspects of product identification for medical products are as follows:

- The product identifier must be unique in the global supply chain, never re-used, and mandated by the FDA to ensure compliance.
- The technology used for carrying the Product Identifier (barcode or RFID) must be based on well-established standards for this technology, and under the ISO framework for such aspects as “air-interface” etc.
- For track and trace, the standards must accommodate a format or method to store lot/batch number, serial number (if appropriate), and expiry date.
- The identifier should be based on a variable-width alphanumeric structure to allow manufacturers to embed actual Manufacturer reference numbers. A regulation that requires actual and widely disseminated reference numbers to be converted or cross-referenced to accommodate more restrictive all-numeric requirements would increase the likelihood of errors and therefore an increased risk to patient safety.

(3) We have observed that the wording of FDA’s request for comments appears to be based upon the assumption that there is to be a **numerical** identifier for medical products. The term “numerical” or “number” is frequently used colloquially to refer to identifiers in general, and HIBCC is thus uncertain if FDA intends to deliberately narrow its definition of product identifiers in this manner. If so, we believe doing so would create a significant limitation in any identification system that would undermine primary FDA’s objective (as described below in our specific comments).

Assuming the use of an established standard to meet these requirements, other processes and functions to insure that products are suitably tracked, traced and validated through the supply chain also depend upon many other factors, including:

- Government regulations and policy that indicates what information is required to be shared for transactions involving medical products.
- Availability and capability of Information and Communications Technology (ICT) across the supply chain.
- Interoperability of systems across the supply chain (i.e. the ability for systems to “talk” to one another).

These issues are far reaching and complex in nature, and require far greater attention than a one-dimensional focus on the product identification standard alone.

**Specific Comments**

Below HIBCC has provided comments to FDA questions that it considers to be within its purview; each is presented in the order in which they appear in the FDA document.
SECTION A – Standard Numerical Identifier

- **Characteristics**
  a) Should the standardized numerical identifier contain recognizable characteristics (e.g. National Drug Code number) or random codes?

HIBCC believes that the identifier should be alphanumeric, and not numeric, as implied in this question. FDA’s premise of a numeric-only approach is technologically obsolete and counter-productive since it would require extensive and risky cross-referencing of millions of existing unique product codes.

HIBCC is of the view that the primary concern in relation to the format of the product identifier should be that it is unique in the global supply chain. This can be achieved through compliance to existing standards published by the International Organisation for Standardisation (ISO). The American National Standards Institute (ANSI) is a member organization of ISO, and under the charter of ISO, National Standards organizations are required to support internationally recognized standards.

Two standards are primarily recognized by ISO for healthcare product identification: ANSI/HIBC and GS1. Appendix A contains a list of companies that have adopted HIBCC labeling standards.

Although the NDC may guarantee uniqueness for prescription drugs in the USA, this numeric identifier alone will not necessarily be unique in the global supply chain. If the NDC is used, it must therefore also be incorporated within a format that ensures its uniqueness.

b) Should there be a common header for item/product segregation based on product type: biologic, solid oral dosage form, etc.?

HIBCC believes that the identifier should not have such a header. This level of information should be required in data taxonomy requirements for medical products.

c) How can parties in the supply chain ensure that numbers are unique and are not duplicated?

Ensuring that identifiers are not duplicated will require that there is a policy set down by the FDA to ensure that they are not re-used in the supply chain for medical products. Because the ANSI/HIBC standard is based on variable width alphanumeric identifiers, this is not an issue for manufacturers that use this standard – since a single LIC issued to a company provides an infinite number of identifiers.

However, this has been a problem for the GS1 GTIN’s. Manufacturers of drugs regularly re-use GTIN’s. This practice occurs when drugs are discontinued by manufacturers, and rather than assigning a new GTIN to new products (which may attract higher fees from GS1), manufacturers re-use identifiers from discontinued product lines for new and different drug products.
d) How much value would there be in having a numerical identifier in more than one place for the product (e.g., package and pallet level)

HIBCC believes that it is essential that each packaging level from the unit of issue through to the largest saleable logistic unit is uniquely identified. However, some discretion is required at the pallet level. There are better approaches to tracking and tracing products at the pallet level. This is generally achieved through the use of serialized transport codes to track such logistical units.

The ANSI/HIBC format for product identification includes a particularly robust approach to tracking each packaging level. Each packaging level is identified by a code from 0 to 9, where “0” represents the unit of issue. “1” through to “8” represents each packing level above the unit of issue. “9” represents a variable quantity package (The use of “9” requires that the quantity of the package is stated in the secondary barcode). This approach ensures that the essence of the identifier for a “like” product remains the same at all packaging levels, with the only one variable in the code being the one-digit packaging level indicator. This ANSI/HIBC approach is thus less ambiguous than an approach, such as that of GS1’s GTIN, where the identifier is completely different for each packaging level.

e) Should the numerical identifier be machine readable, human readable, or both?

As previously stated, HIBCC believes that the product identifier should be both machine and human readable wherever practical. There may be circumstances in which it is not feasible to have a machine readable code, due to physical attributes or technical limitations. Where this is the case, the product should nevertheless have a human readable identifier.

f) Should the numerical identifier include the lot/batch number?

Yes. The product identifier should include the lot/or serial number as appropriate. This data is generally included in “secondary” data structures either in a separate barcode or identifier, or in a concatenated format. The format for the secondary data may also include other data attributes, including but not limited to expiration date and quantity. It should also allow for alphanumeric lot/batch or serial numbers.

2.0 Standards

a) Do standards currently exist for a standardized numerical identifier of prescription drugs?

Standards around product identification are not specific to prescription drugs, but rather are applicable across different product groups, including medical devices and other consumable products. The key important attributes for a product identifier are:

- That the identifier accommodates alphanumeric characters, and is of variable width.
- There is a package level indicator to ensure that all distinct packages, including the unit of issue can be uniquely and easily identified for “like” products.
• The identifier is unambiguous, and unique in the supply chain.
• The identifier is not re-used.
• The standard has attributes that allow secondary data to be captured, including lot/batch number, serial number and expiry date (for example).

These attributes are encapsulated within the ANSI/HIBC standard, and are supported by ISO and ANSI publications.

However, the predominant implementation for prescription drugs by manufacturers has been the EAN.UCC (now GS1) standard in the EAN13 (now GS1-13) variant. This is because the majority of prescription drugs are distributed through retail pharmacy, where the GS1-13 is the predominant standard for cash-register applications. The GS1-13 is very limited, and does not include the desired characteristics as stated previously:

• The GS1-13 is a fixed-width all numeric identifier. This limitation has frequently resulted in the “re-use” of numbers, hence causing duplication in the supply chain. This practice is a high risk practice that can lead to patient safety issues.
• The GS1-13 does not include a package level indicator. Thus, there is no commonality in numbers between the various packaging levels for “like” products.
• The GS1-13 does not include crucial secondary data such as lot/batch and expiry date. This makes track and trace applications more difficult to achieve, since the capture of this information can only be achieved through error prone, manual data entry processes.

b) Are standards in development or planned for standardized numerical identifiers of prescription drugs in the supply chain? If so, who is developing these standards and what is the timeline for completion


This standard resulted from work carried out by Massachusetts General Hospital (MGH), a hospital within the Partners Healthcare System. MGH embarked on a project in 2004 to develop a safer system for the administration of medication to patients. The proposed system and resulting specification requires the use of “barcodes”, “2-D” symbols or RFID tags to automatically capture data, thereby reducing transcription / data entry errors and improving patient safety. The standard addresses many aspects of the safe delivery of medication within the provider setting including:

• Automatic data capture of employee identification – to ensure positive identification for staff administering drugs.
• Automatic data capture of patient ID – to ensure positive identification of patient.
• Non-IV medications. Information contained in Non-IV medication barcodes for identification and tracking. The information is at the unit of issue to the patient, using 2-D symbology (E.g., Datamatrix).
• IV Medications and Smart Infusion Pumps. Information contained in Non-IV medication barcodes for identification and tracking. This may also include patient specific information and order information to program a smart infusion pump.

HIBCC developed this standard with the understanding that the supply chain for medical products – particularly medications and medical devices – cannot be addressed in isolation of the clinical applications. This standard addresses many of the issues associated with the safe delivery of medications to patients within a healthcare provider setting, and it has far reaching applications to the supply chain. The standard has been published by ANSI, and is maintained by HIBCC.

c) What are the elements, provisions, and particular considerations that should be included in a standardized numerical identifier of prescription drugs?

Addressed in a) above

d) Please comment on any technical or information technology concerns related to standardized numerical identifiers

While the product identifier is an important component to systems for achieving the desired benefits, it is only a small component of the overall system. The identifier alone will not contribute to these benefits. The other components that are required to achieve the desired benefits include, but are not limited to:

• Information management systems (software and hardware) with the appropriate functionality for the task required, e.g. materials management and purchasing software, enterprise resource planning systems, patient administration systems etc;
• Information systems designed to support the identifier and associated databases;
• Data model and data dictionaries incorporating the data required for the particular applications, referencing (or cross mapped) to the identifier;
• Systems and processes for “synchronizing” core product data from manufacturers catalogues through the entire supply chain;
• Systems integration – so that the different applications within healthcare using the identifier are integrated and not independent;
• Education, training and good management.

e) Comment on any “lessons learned” from foreign experience with standardized numerical identifiers.

Those standards based upon fixed-width all numeric formats have failed to achieve international harmonization because as the number of items to be identified has grown, the available pool of “numbers” has been insufficient to accommodate them. This problem has led to variations in format length (number of characters) by region and/or country, “backfilling of “zeroes” to change lengths, etc. This has led to a counter-productive balkanization of standards.
3.0 Economic Impact

a) What are the usual practices and associated costs that now exist for applying bar codes and other technologies for standardized numerical identifiers on packages and pallets?

HIBCC can only comment on the process for applying standard product identifiers, and only comment in general on the associated costs.

Manufacturers of medical products apply for a unique Labeler Identification Code (LIC) from HIBCC, or a company prefix from GS1. The HIBCC fee is a once-only payment which is scaled to the size of the organization, so as to include even the smallest of labeling companies. We believe any fee structure that requires annual payments or payments in numerous countries is unnecessarily prohibitive and therefore discourages the use of standards. Within HIBCC, a single LIC can be purchased irrespective of the quantity of identifiers required by the labeler. HIBCC firmly believes that standards organizations, by virtue of their position in the marketplace and non-profit status, should not seek to benefit financially from their unique position. FDA requirements should not inadvertently create an unregulated monopoly environment in the standards “marketplace”.

The setup costs in implementing a standard product identifier system will vary depending on:

- the size of the organization,
- the complexity of the products manufactured, and
- the size and complexity of the distribution chain.

For example, multi-national companies that manufacture and distribute in many countries, using a variety of distribution models, and subjected to country specific regulation in the markets they distribute, will find the implementation of the identifier complex, challenging, and expensive. This would be particularly the case should the standard recommended not conform to existing, internationally accredited standards.

b) What are the associated costs for the application, use, and maintenance of standardized numerical identifiers?

See comment above

c) What are the associated costs of processes for updating the standards as needed?

See comment above

d) What are the benefits of using Standardized numerical identifiers?

The standard product identifier is an important component for improving processes for Track and Trace, validation, authentication and patient safety for prescription drugs.

However, while a cornerstone, the standard identifier alone is but one component of the systems required. A clear direction on the standard identifier provides consistency that will likely facilitate the development of IT systems, which in turn provides for uniformity across healthcare.

Equally important is that standard and consistent guidelines and specifications are developed for:
• Patient administration systems in relation to prescription drug tracking;
• adverse event reporting;
• Data models and specifications for the static and dynamic data required for the different applications;
• Purchasing and inventory control.

Also equally important is that IT investment in healthcare is increased in order that systems are developed and upgraded to take advantage of available technologies and standards. This investment will take some time, and improvements and benefits will be incremental in nature.

4.0 Harmonization with other countries

Please refer to previous comments related to ISO standards.

SECTIONS B, C, D AND E

HIBCC has elected not to respond to these sections, as it is our view that these sections are beyond the scope of standardization for unique identifiers. Where there is relevance to track and trace systems, for example, and a direct link to unique identification, we have addressed this in Section A.

Submitted on behalf of HIBCC by:

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The following companies (and/or their subsidiaries/divisions) have applied for Labeler Identification Code (LIC) assignment registration through HIBCC or one of its international affiliates. These organizations have demonstrated their support of HIBCC’s goal of implementing auto-ID technology and achieving health care improvement. We applaud these organizations for their commitment to customers, the industry, and their future.

Any organization — manufacturer, distributor, wholesaler, hospital or other health care organization — interested in using the HIBCC uniform labeling system may apply for assignment of one or more LIC. For more information, please contact the HIBCC office at:

2525 E. Arizona Biltmore Circle
Suite 127
Phoenix, AZ 85016
TEL: 602.381.1091
FAX: 602.381.1093
E-mail: info@hibcc.org
Web: www.hibcc.org

APPENDIX A

Australia
Bioclone Australia Pty Limited
Depuy Australia Pty Ltd
Medical & Surgical Requisites
Smith & Nephew Surgical
Southern Dental Industries
Thermo Electron Corp
Willam A. Cook Australia Ltd.

Medical Engineering
S&G Implants GMBH
Zimmer Ltd.

China
Johnson & Johnson Medical

Danmark
Coloplast A/S
Contura International A/S
Radiometer Medical A/S

Finland
Bionix Implants OY
Inion Ltd.
Komi-Set OY
Mediala OY
Organium Laboratories
Sataside OY
Tyke-Tuote

France
ATF-Vitatech
Becton Dickinson France
Benoit Girard et Cie S.A.
Bioland
Biomatlanle
Bimerieux S.A.
Dentsply France SAS
Ethicon SAS France
Ethnor S.A. France
Groupe Lepine
Hexacath SARL
Helioscopie-Ceerdil
Hospal International
Ioltech Laboratories
Johnson & Johnson Medical
Kasios
LDR Medical
Landanger-Landos
Medicrea
Micro-Mega S.A.
New Deal
Pierre Rolland
Sarl Biomatlanle
Satelec

Finland
Bionix Implants OY
Inion Ltd.
Komi-Set OY
Mediala OY
Organium Laboratories
Sataside OY
Tyke-Tuote

France
ATF-Vitatech
Becton Dickinson France
Benoit Girard et Cie S.A.
Bioland
Biomatlanle
Bimerieux S.A.
Dentsply France SAS
Ethicon SAS France
Ethnor S.A. France
Groupe Lepine
Hexacath SARL
Helioscopie-Ceerdil
Hospal International
Ioltech Laboratories
Johnson & Johnson Medical
Kasios
LDR Medical
Landanger-Landos
Medicrea
Micro-Mega S.A.
New Deal
Pierre Rolland
Sarl Biomatlanle
Satelec

Germany (Deutschland)
Abbott Vascular Instruments
Aesculap A.G.
B. Braun Melsungen A.G.
B. Braun Surgical GmbH
BEGO GmbH & Co.
Beiersdorf Inc.
Bosch & Sohn GmbH & Co.
Chem. Pharmazeutische CROMA GmbH
Dentaurum J P Winkelstroet
Dentsply GmbH
Dr. Jean Bausch KG
E. Hahnenkratt GmbH
ESPE Dental-Medizin GmbH
Espirident GmbH
Ethicon GmbH Germany
Fotochemische Werke GmbH
Girrbach Dental GmbH
Heraeus Kulzer GmbH
Howmedica GmbH
Howmedica Leibinger GmbH
Johnson & Johnson Medical
Karl Storz — Endoskope
Lohmann GMBH & Co.
Merz + Co.
Merz Dental
Noba Berbandmittel Danz GmbH
Orochemie Durr + Pflug GmbH
PVB Medizintechnik
GmAccessH
Renfert GmbH
Resorba Chirurgisches Naht
Richter & Hoffmann Harvard
ROEKO GmbH + Co.
Schu-Dental
Scheu-Dental
Serag-Weissner GmbH
Tiolox Implants GmbH
Vita Zahnfabrik

Canada
ECI Medical Technologies Inc.
Johnson & Johnson
Iolab Canada Inc.
Janssen Pharmaceutica Inc.
Johnson & Johnson Medical
McNeil Pharmaceutical
Ortho Diagnostic Systems
Ortho Pharmaceutical Corp.
Numed Canada Inc.
PriMed Instruments Inc.
Primeline Medical Products Inc.
The Westaim Corporation
Vivosonic Inc.
Zimmer Inc.
Arthroscopy Systems
Astell

Sofradim Production
Surfix
Tornier
Vitalitec International

Austria
Bender MedSystems GmbH
Dentalwerk BURMOOS GmbH

Belgium
3M Europe
Centean Benelux N.V.
Cilag N.V.
Coris Bioconcept
GC Europe N.V.
Johnson & Johnson International
Menarini Benelux S.A./N.V.
Molnycke Europe S.A.
Schering-Plough B.V.

Bosch & Sohn GmbH & Co.
Chem. Pharmazeutische CROMA GmbH
Dentaurum J P Winkelstroet
Dentsply GmbH
Dr. Jean Bausch KG
E. Hahnenkratt GmbH
ESPE Dental-Medizin GmbH
Espirident GmbH
Ethicon GmbH Germany
Fotochemische Werke GmbH
Girrbach Dental GmbH
Heraeus Kulzer GmbH
Howmedica GmbH
Howmedica Leibinger GmbH
Johnson & Johnson Medical
Karl Storz — Endoskope
Lohmann GMBH & Co.
Merz + Co.
Merz Dental
Noba Berbandmittel Danz GmbH
Orochemie Durr + Pflug GmbH
PVB Medizintechnik
GmAccessH
Renfert GmbH
Resorba Chirurgisches Naht
Richter & Hoffmann Harvard
ROEKO GmbH + Co.
Schu-Dental
Scheu-Dental
Serag-Weissner GmbH
Tiolox Implants GmbH
Vita Zahnfabrik
Hungary
De-Puy Sanatmetal Mfg.

Ireland
Abbott Vascular Devices
Abbott Ireland Limited
Allergan, Inc
Howmedica International Ltd.
Howmedica International Inc.
Fujisawa GmbH
Johnson & Johnson Prof.
Products
Mednova
Proxy Biomedical Ltd.
Stryker Ireland (Cork)

Italy
Adaltis Italia SPA
Bioret SRL
Coppa Italia Spa
Critikon - Johnson & Johnson
DiaSorin S.R.L.
Dideco SpA
Dia Pro Diagnostic Dioprobes Srl
Gambro SpA
Johnson & Johnson
Medical Holdings, SpA
Kerr Italia SpA
LIMA-LTO SPA
MD & I SRL
MedicalPlastic S.R.L.
RS Medica SRL
Sire Analytical Systems
Sorin Biomedica Cardio SpA

Japan
GC Corporation
Fuji Photo Film Company Ltd.
Konica Corporation
Terumo Corporation

Korea
U & I Corporation

Liethenstien
Ets Vivadent
Ivoclar A.G.

Mexico
Mallinckrodt Medical Inc.
Mallinckrodt Medical TPI

The Netherlands
Abbott B.V.
Academisch Zkh. Maastricht
Alcon Pharmaceutical Ltd.
Astra Pharmaceutical Prod. Inc
Bayer Nederland B.V.
Bipharma B.V.
Boehringer Ingelheim B.V.
Boots Pharmaceuticals B.V.
Bournonville-pharma B.V.
Brocacef B.V.
Brocacef B.V.
Bufa — Chemie B.V.
Byk Nederland B.V.
Centrafarm
Central Lab V.d.
Bloedtransfusiedienst
Christiaens B.V.
Dg Lederle Nederland B.V.
Dumex B.V.
Duphar Nederland B.V.
E.Merck Nederland B.V.
Elly Lilly Nederland B.V.
Farmaceutische Ond.
Lansberghortdam
Genfarma
Gist Brocades
Glaxo B.V.
Guerbet Nederland B.V.
HandelsONDerneming
Tempus B.V.
Hoechst-holland N.V.
Ici-farma
Inpharzam/Zambon
Nederland B.V.
Interpharm B.V.
Janssen Pharmaceutica B.V.
Johnson & Johnson Medical B.V.
Kabi Pharmacia B.V.
Katwijk Farma B.V.
KnmP
Knoll B.V.
Koninklijke Utermohlen N.V.
Lundbeck B.V.
Magnafarma B.V.
Menomfa B.V.
Medicopharma N.V.
Medport BV
Merck Sharp & Dohme B.V.
Multipharma
Novo Nordisk Farma B.V.
Npbi B.V.
Onderlinge Pharm
Groothandel U.A.
Ortoned B.V.
Parke-Davis B.V. Division
Warner Lambert
Pfizer B.V.
Pharbita B.V.
Pharmachemie B.V.
Polyfarma B.V.
Rhone-poulenc RorerPharbil
Roche Nederland B.V.
Rooster & Zn. B.V.
Samenwerken Apotheekers
Nederland
Sandoz B.V.
Sanofi B.V.
Schering Nederland B.V.
Searle Nederland B.V.
Smithkline Beecham Farma
St. Volksgez En Milieuhygiene
Stephan B.V.
Stephim B.V.
Taxandria Pharmaceutica B.V.
Tramedico B.V.
Upjohn Nederland - Ede
Van Den Berg Nederland B.V.
Wellcome Pharmaceuticals B.V.
Wyeth Laboratoria B.V.
Zyma-nederland B.V.

New Zealand
Enztec Limited

Norway
Nycomed Imaging AS

Portugal
Johnson & Johnson Produtos Prof.

Puerto Rico
Puerto Rico Hospital Supply Inc.

South Africa
Johnson & Johnson Medical
Ortho Sol (Pty) Ltd

Spain
Howmedica Faimon S.A.
Howmedica-Iberica S.A.
Johnson & Johnson
Productos Prof.
Metalor Iberica

Sweden
Carmel Pharma AB
Gamboo A.B.
Lic Hygien A.B.
Medscand Medical A.B.
NobelPharma

Switzerland
abien-Air S.A.
Assut Medical Sarl
Candulor A.G.
Central Labs Blood
Transfusion Svs.
Coltene A.G.
Degradable Solutions AG
Hamilton Medical AG
Hospit Ltd.
Jaquet Orthopedie S.A.
Maillefer Instruments S.A.
Metaux Precieux S.A.
Metalor
Precimed S.A.
Prodonta SA
Produits Dentaires S.A.
Schneider (Europe) A.G.
Swemac Orthopaedics AB
Tip Top Tips Sarl
UGDO S.A.
UNOR AG
Valtronic

Turkey
Alter Bibi Malzeme San Ve Tic As

United Kingdom
3M Health Care Limited
B Braun Melsungen AG
Downs Surgical
BOC Health Care
Boc Health Care
Corin Ltd.

United States
3M
3M Med/Surg
A-DecInc.
Aaron Medical Industries Inc.
Bovie Medical
Aastrom Biosciences
Abbott Laboratories
Abo Dealers Inc.
Ability One Corporation
Absorbent Products
Company Inc.
Access Closure, Inc
Ace Medical
Acme United Corporation
Acumed Inc.
Acute Biomedical Inc.
Adroit Medical Systems
Ad-Tech Medical Instrument Corp
Advance Medical Designs Inc.
Advanced Biomaterial Systems
Advanced Bionics, LLC
Advanced Medical Optics
Advanced Meditech
Advan DX, Inc
International Inc.
Advanced UroScience, Inc.
A&E Medical Corporation
Aesculap Instruments Corp
AFP Imaging Corp
Dent-X Corp
AGA Medical Corporation
Agfa Corporation
Matrix Division
Air Techniques Inc.
All-Pro Imaging Corporation
Jelrus International Corporation
Akzo Pharmaceuticals
Organon Teknika
Alba Health Products
Alcide Corporation
Alcon Laboratories
Allergan Inc.
Alliant Enterprises Inc.
Allo Source
Amcol International
Chenndal Corp
American Australian ME
American Cyanamid Company
Davis & Geck
American Dental Cooperative
American Dental Supply Inc.
American Home Products Corp
Argyle Div of Sherwood Medical
Dover Urologicals Div of Sherwood Medical
Monject Div of Sherwood Medical
Oxford Chemistries Div of Sherwood Medical
Oxford Lab Supplies Div of Sherwood Medical
Oxford Liquid Handling Div Sherwood Medical
Sherwood, Davis & Geck
Veterinary Div of Sherwood Medical
US Clinical Products
Wyeth-Ayerst Laboratories
Amersham Health
Amsino International Inc.
Anatomical Concepts Inc.
Angioscore Inc.
Anika Therapeutics Inc.
Anesthesia Medical
Specialties Inc.
Angelion Corporation
Angiodynamics
E-Z-EM Inc.
Angioguard Inc.
Angiotech Biocarangers Corp
A-Plus International
Applied Medical Resources
Applied Spine Technologies
Apotex Laboratories Inc.
Armoire Pharmaceutical Co.
USV Laboratories Division
USV Pharma Corporation
Arrow International Inc.
Arrow Precision Products
Arterial Vascular Eng Inc.
Arthrex Inc.
Arthrotek
Artherosurface, Inc
Aspen Surgical Products Inc.
Astra USA
Athena Champion
Atricure, Inc.
Atrium Medical Corporation
ATS Medical Inc.
Audit Microcontrols Inc.
Auric Enterprises
Diack
Austenal Dental Inc.
Nobel Pharma USA
Automated Medical Products Inc.
Automatic Liquid Packaging Div
Healthcare Products Div
Avanti Systems Inc.
Avid Medical, Inc.
Axis Dental Corp
AXO Gen, Inc.
Bacchus Vascular
Bacharach Inc.
Bacterin International
Banta Healthcare
Baron Medical Corporation
Barriemed Inc.
Barriemred Glove Co.
Barx Medical Inc.
Bausch & Lomb
Surgical Division
Bayer Corporation
Agfa Division
Baxa Corporation
Baxter Healthcare Corporation
Midwest Textiles Inc.
B. Braun Interventional Systems
B Braun Medical Inc.
Burrn Mfg Div
B Braun Melsungen AG
Downs Surgical
Beckman Coulter Primary Care Diagnostics
Beckman Coulter Inc.
Becton Dickinson & Company
Acucare Division
Diagnostic Instrument Systems
Immunocytometry Systems
Infusion Systems
Labware Division
Medical Glove Division
Medical Technique Products
Microbiology Systems
Pharmaceutical Systems
Vacutainer Systems
Beiersdorf Inc.
Jobst Institute
Beiersdorf Medical
Bel-Art Products
Maddak Inc.
Belport Company
Ginipak
Bemis Health Care Inc.
Bemis Manufacturing Company
Bergen Brunswig Corporation
Berkeley Medical Resources Inc.
B G Industries Inc.
Biddle & Crowther Company
Biocompatibles
International PLc
Biocompatibles Cardiovascular Inc.
Biocomposites LTD
Bio Compression Systems
BioDerm Inc.
BioForm Medical Inc.
Biofab Diagnostics S/A
Biological & Environ.
Control Labs
Biomed Diagnostics Inc.
Biomed Packaging Systems Inc.
Bioplaste Inc.
Bio-Medical Devices Inc.
Bio Medical Enterprises, Inc
Bio Plas Inc.
Bio-Plexus, Inc.
Bio-Pro
Bio-Rad Laboratories Inc.
Bio-Rad Medianation Operation
Biosculpture Technology Inc
Bioseal Medical Packaging Concepts
Biosearch Medical Products Inc.
Biosphere Medical Inc.
Biotechn Instruments, Inc
Biotrol International
Pro-Dex Inc.
Birchwood Laboratories Inc.
Blackstone Medical, Inc.
Block Medical Inc.
Blue Medical Devices BV
Boehringer Laboratories Inc.
Boekel Industries Inc.
Boots-Celltech Diagnostics Ltd.
Bound Tree Medical
Boston Scientific Corporation
Advanced Bionics
Cardiac Assist
Brennen Medical Inc.
Brevoen Inc.
Bridge Biomed Inc.
Briggs Medical Service Corp
Brinkmann Instruments Inc.
Eppendorf Scientific, Inc.
Buffalo Filter
Bulbtronics Inc.
Busse Hospital Disposables
CHM Medical Products Group
C R Bard Inc.
Cardiac Assist Systems
Cardia Inc.
Cardinal Scale Mfg Co.
Dentec O Scale
Cardiogenesis Corporation
Cardiomedms Inc.
Cardiovascular Innovations LLC
Careplus (M) SDN. BHD.
Careside Inc.
Carl Parker Associates Inc.
Dental Materials Group
Mydent Corp
Castle Professional Services Inc.
Cardio Medical Solutions Inc.
Cayenne Medical, Inc.
Centrix Incorporated
Century Plastics
Mac-Lee Medical Products
Cetylite Industries Inc.
Chatsworth-Latex Inc.
Cheesbrough-Ponds Inc.
Home Services Division
Chester Labs Inc.
Chiron Vision
Chris-Craft Industrial Products
MD Industries Inc.
Churchill Medical System Inc.
Ciba Corning Diagnostics Inc.
CIDA
Cincinnati Surgical Company
Circon Corp
Cobalt Medical Corporation
Civco Medical Instruments
Clearmedical Inc.
Clinical Innovations Inc.
Clinical Instruments Inc. Inc
Clinimed Incorporated
Mortara Instrument, Inc
M-Pact Worldwide, LLC
MPS Acacia
MRLB International, Inc.
Nanogen Inc.
Nanoscale Materials Inc.
National Distrib. & Contracting Inc.
National Keystone Products Co.
Mizzy Inc.
National Standard Company
Medical Products Division
Natus Medical
NDM-New Dimensions In Medicine
Neo Devices, Inc.
Neptune Products Inc.
Neucoll
Neuhauß Laboratories Inc.
Neurocovery
Neurovasx Inc.
Newell Rubbermaid Inc.
Newtix Industries Inc.
Nexcore Technology
Nexus Medical LLC
Nice-Pak Products
Professional Disposable Inc.
Niche Medical
Ni-Med Inc.
Nordent Manufacturing
Norian Corp
Norma Tec Inc.
North Coast Medi-Tek Inc.
Northeast Scientific, Inc.
Norton Company
Novolette Corporation
NuMed Inc.
NxStage Medical Inc.
Oasis Medical
O-Two-Systems International
Ohaus Scale Division
Olson Medical Sales Inc.
PSC of Kentucky
Omega Medical Products Corp
Omega Surgical Instruments Inc.
Omni-Flow Inc.
Omni International, LLC
Omnisonics Medical Technologies
Omnifit Industries Inc.
Ongoing Care Solutions
Ophthalmic Innovations International Inc.
Opus Medical Inc.
Optical Radiation Corporation
Opticon Medical
Ora Innovations Inc.
Orbus Medical Technologies Inc.
Ortho Medsystems Inc.
Ortho Development Corporation
Orthofix Inc.
Orthopedic Systems Inc.
Ortho Technology
Origen Biomedical
Oscar, Inc.
Ostex International Inc.
Owens-Illinois Inc.
Owens-Briargam
Owens-Illinois Health Care Group
Pacific Hemostasis
Curtin Matheson Scientific Inc.
Packaging Services Corp.
of Kentucky
Q2 Medical
Pall Corp
Pall Biomedical Products Co.
Palmero Health Care
Pascal Company Inc.
Pathway Medical Technologies, Inc
Patterson Dental Company
PDI/Professional Disposables International
Pearson Dental Supply
Peerless International Inc.
Perclose Inc.
Perfeceal
Medi-Plus
Perigon Medical
Distribution Group
Pfizer Hospital Products Group
American Medical Systems Inc.
Howmedica Inc.
Schneider USA
Vallelyab Inc.
Pharma-Plast Inc.
Pharma-Plast Denmark
Pharma-Plast USA
Philips Medical Systems
Picker International
Pilling Weck
Pinnacle Products Inc.
Plastek Industries Inc.
Plasti-Products Inc.
Poly Vac
Polyten LLC
Pope Scientific
Porex Technologies of Georgia
Porex Surgical Inc.
Porton Diagnostics Inc.
Porton International PLC
Pouch Support Systems Inc.
Power Medical Intervent
Practicewares Dental Supply
Precision Dynamics Corp
Precision Laboratory
Plastics Inc.
Precision Scientific Inc.
Precision Systems Inc.
Precision Vascular Systems
Premier Dental Products Co.
Premium Plastics Inc.
Presby Corp
Preventive Technologies
Principle Industries, Inc.
Professional Care Products
Professional Hospital Supply Inc.
Professional Medical Products
Professional Products Inc.
Government Sales Div
Professional Tape Company Inc.
Time-Med Labeling Systems
Prograff Medical Inc.
Progressive Dynamics Inc.
Proma Inc.
Proper Manufacturing Co. Inc.
Protocol Systems Inc.
PSS World Medical
PT. Eka Wira Asia
Puerto Rico Hospital Supply
Pulmonetics, Inc.
Pulpdent Corporation
Pymah Corporation
ATT Division
Qorpak
QRS Diagnostic LLC
Quantimetrix Corporation
Quinton Instrument Company
Div of American Home Products
Quintus Inc.
Radius Medical Technologies
RD Medical Manufacturing Inc.
Reckitt & Colman Inc.
R & C Probrands
Respironics
Restore Medical, Inc.
Richard-Allan Medical Industries
Richard-Allan Scientific
Rinn Corporation
Roche Diagnostic Systems
Roxane Laboratories Inc.
Royce Medical
Sabratek Corporation
Rocap
Sadra Medical Corporation
Safco Dental Supply Co.
Safety Medical
International Inc.
Saf-T-Med
Sage Products Inc.
Sakura Finetek USA Inc.
Samco Scientific Inc.
Sarlight Biomatlante
Savannah River Mills Inc.
SBW Medical Products Inc.
Scandius Biomedical Inc.
Schleicher & Schuell Inc.
Schwarz Pharma
Kremers Urban Company
Sci Tech Dental Inc.
Science Incorporated
Scienx Scientific
Scimed Life Systems Inc.
SeaPharm, Inc
Sempermed USA Inc.
Senox Inc.
Septodont Inc.
Seraday Inc.
Mitsubishi Kasei America Inc.
Serim Research Corporation
Sorokin Scientific Specialty Sys
Sharon Metal Stamping Corp
Walk On Air
Sharkids Eye Gear
Sharn Inc.
Sheldon Manufacturing Inc.
Siempelkamp Medical Technologies
Sigma Rx LP
Sil-Med Corp
Skedco Inc.
Skil Corp
Smart Medical Technology, Inc.
Smartcare
Smart Practice
Smartpill Corporation
Smith & Nephew Inc.
Endoscopy Division
Orthopaedic Division
Rehabilitation Division
Wound Management Division
Sonnus Medical Technologies
Sonic Innovations, Inc
Sony Corporation
Sorb Technology Inc.
Sorin Biomedica
COBE Cardiovascular Inc.
Sorin Biomedical Inc.
Sota Medical Products
Southern Dental Industries
Spacelabs Inc.
Spacelabs Medical Inc.
(Deerfield)
Spartan Medical Products, LLC
Sparta Surgical Corp
Maxillofacial Products Inc.
Span-America Medical Systems Inc.
Specialized Health Products
Specialty Surgical Instrumentation
Spectrum Designs Medical
Spectrum Medical Industries Inc.
Spectranetics Corporation
Spinal Kinetics
Spire Corporation
Sporicidin International
SS White Burs Inc.
St. Jude Medical, CRM
St. Jude Medical, Daig Division, Inc.
Staco Energy Products Company
Standard Register
Advanced Medical Systems
Stanley Works
Jensen Tools Inc.