DENTAL MANUFACTURERS OF AMERICA, INC.
FOUNDED 1932

123 South Broad Street • Suite 2030 • Philadelphia PA 19109-1020
(215) 731-9975 or 731-9982 • Fax: (215) 731-9984
www.dmanews.org • e-mail: staff@dmanews.org

OFFICE OF THE EXECUTIVE DIRECTOR
EDWARD B. SHILS, J.D., LL.M., Ph.D., S.J.D.

June 22, 2001

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, rm. 1061
Rockville, MD 20852

Re: Docket No. 01N-0191

Gentlemen:

The Dental Manufacturers of America, Inc. has more than 230 members ranging from small entrepreneurs to large corporations. We wish to comment on the recent proposal by the Global Harmonization Task Force Study Group 1, which advocates a simple rules-based risk classification system. We believe that this classification method fails to address the needs of American industry and the American public. The attached document on the GHTF SG-1 proposal carefully examines SG1/N015R14 as opposed to the current method employed by the U.S. Food and Drug Administration. A comparison chart in the briefing shows that the SG-1 proposal re-classifies dental devices nearly 50% of the time to a higher or lower level than has been determined by impartial expert panels who specifically reviewed medical device risks and made recommendations for classification which were considered and adopted by the FDA.

The attached briefing also compares both SG1/N015R14 and European Directive 93/42/EEC regarding medical device classification. The DMA has taken the time to clearly establish that the GHTF has simply adopted the EU system rather than adopting the current US system or developing a more suitable system for classifying devices.

Medical Device Classification is the basis of regulations that follow. Adoption of SG1/N015R14 is a step toward global CE marking, which fails to address the important needs of manufacturers who provide low and medium risk medical devices. Study Group 1 has failed to address the needs of industry in the following ways:

1) Rules-based risk classification does not provide for any method of changing specific medical device requirements or controls that may be needed to protect life or reduce onerous regulation.

   The time-tested classification method of the FDA has allowed for reducing the regulatory burden of devices that have proven to be of lower risk than previously decided by the panels of experts. With few exceptions, Class I devices are now exempted from 510(k) requirements, and from onerous Design Controls of the GMP (QS) regulations. Even some Class II devices also have been exempted from 510(k) requirements. This has reduced the regulatory and financial burdens on hundreds of medical device manufacturers, while maintaining safety for consumers.

2) SG1/N015R14 uses arbitrary "rules" to crudely assess risk. Are all "orifices" to be treated the same? Are all patients to be treated the same? The general problem with the EU/CE system is that regulatory experts, even acting in good faith, will arrive at different risk classifications for many devices. This results in unequal and inaccurate regulation of the devices and risks to the patients.

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The FDA carefully examines Medical Device Reports (MDR) and makes changes as needed to specific medical device classifications. European Directive 93/42/EEC Annex 9 provided the basis for the SG-1 proposal for assessing medical device risk classification. Their proposal is equally unable to accommodate specific problems with specific devices being used for a specific intended use.

We do not believe that the GHTF should have proposed guidelines that cannot accommodate device specific changes to risk class. This proposal is bad for industry and does not adequately provide the necessary means for determining the controls needed to protect public citizens.

This brief summary of our comments is designed to be helpful in pointing out major errors in the proposal. It is by no means comprehensive—we refer you to the following document for a more complete discussion of this proposal. Your consideration will be sincerely appreciated.

Sincerely,

George Wilke

George Wilke
President

Edward B. Shils

Edward B. Shils, SJD, JD, LLM, Ph.D
Executive Director

cc: DMA Officers & Directors
DMA Regulatory/Technology Committee

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DMA
Regulatory Affairs
And Technology
Commitee

Guidance for Government &
The International Dental Industry

Briefing:
Global Harmonization
Task Force activities:

Study Group 1
Medical Device Risk Classification

Reference to GHTF
Document Number: SG1/N015R14

FDA Public Docket Number 01N-0191
May 24, 2001

Prepared by:

Grant Ramaley Associate Chairman,

Regulatory Affairs and Technology Committee

Dental Manufacturers of America.

Preface

Objectives of the GHTF Briefing

The Dental Manufacturers of America (DMA) continues to provide its members and United States Government representatives its perspective on regulations affecting the global dental sector. The DMA's objective to find affordable means to overcome foreign trade barriers and to resolve other problems for dental manufacturers in order to provide a better understanding of how global medical device regulations impact small and medium sized businesses.

The regulatory guidance being proposed by the Global Harmonization Task Force (GHTF) plays an important role in international trade agreements. The current draft of the MRA between the United States and European Union includes several references to GHTF documents. These documents are intended to resolve differences between countries by proposing a consensus on specific issues pertaining to medical device regulations.

Because GHTF documents are intended to harmonize medical device regulations worldwide, they are arguably the most potent force in determining future regulations affecting medical devices. This brief includes a background on where these documents originated and how they may affect industry's ability to sell products domestically and abroad. Since the GHTF's approach has been to mirror the Directives adopted by the European Commission, a comparison between the EU and GHTF documents has also been included. A thorough description of how the four-year old European system has failed to adequately provide for the needs of American industry and public safety concerns is included in the DMA's reports on the MRA. The Dental Manufacturers of America believes that the GHTF must reconsider modeling their proposed documents after the European model.

The DMA is also very concerned with the lack of participation or representation currently being provided to small and medium sized industry representatives at GHTF discussions. In fact all of the individuals who participate as industry representatives to the GHTF's Study Group 1 are from very large corporations that manufacture high risk devices including: cardiac implants, pacemakers, artificial kidneys and neonatal life supporting devices. Although we believe their voice is important to these discussions, Study Group 1 has demonstrated a disappointing lack of concern for the largest population of industries which are comprised of small and medium sized businesses making low and medium risk devices.

GHTF Proposed Medical Device Classificaton

Background

Classification of Medical Devices:

Risk classification is a critical factor regulating medical devices. It is the looking glass by which industry and regulatory authorities view conformity requirements. Medical devices are generally assigned a higher risk classification and require commensurate levels of regulatory controls. In the simplest terms, regulatory controls for manufacturers of cardiac pacemakers are much greater than the regulatory controls imposed on manufacturers of toothbrushes. The methods by which medical devices are classified by the regulatory authorities in the United States and European Union differ in many significant ways.

FDA System For Determining Risk Classification:

The FDA regulates medical device classifications by assigning particular risk classifications to specifically named devices having a specific intended use. The FDA uses impartial panels of experts in specific fields, such as "dental panels" for dental devices to determine the level of risk. These risk classifications then become part of codified regulations. Classified devices include a classification name, a brief description of the device and regulatory controls or exemptions, and finally a risk classification number of: 1 for low-risk, 2 for medium-risk and 3 for high-risk devices. The FDA has codified hundreds of carefully evaluated devices into these risk classes. This system provides opportunities to review and change certain device risk classifications as experience is gained over the years. Under the Freedom of Information Act (FOIA), panel meetings are posted on the Internet for public and industry comment. New devices are given careful attention by all parties that will be affected by the new regulations. Though this process is arguably slower than the European system, it is the most effective method for assessing risk classification.

The GHTF (European) System of Determining Risk Classification

As demonstrated in the highlighted area below, the GHTF guidance for medical device classification documents are nearly identical to the existing European system, even using identical language for the same "rules". The GHTFproposal to adopt the European model will lead to problems that are already creating problems for both industry and public health within their economic area. A background on the EU system has been provided so that it can be clearly understood how this system fails to provide adequately for industry and public health concerns.

The existing European system for classifying medical devices relies on the manufacturer to correctly apply specific "*rules*". There are 18 rules governing all medical device classifications in Europe. If an individual is not well acquainted with this system, he/she must learn the meanings of key *definitions* in the rules and then determine whether a particular *rule* adequately relates to their medical device. Highlighted below are several key words that the manufacturers must understand before determining how to apply the following classification rules.

European Directive

From Council Directive 93/42/EEC, Annex 9, Rule 5
*All **invasive devices** with respect to **body orifices**, other than **surgically invasive devices** and which are not intended for connection to an **active medical device**, are in Class I if they are intended for **transient** use"*

GHTF Document

(SG1/N015R14) Section 8, Rule 5.
All invasive devices with respect to body orifices, other than surgically invasive devices and which are not intended for connection to an active medical device:
- are in Class A if they are intended for transient use.

Rules-based classification systems do not address the risk of a specific device but merely assume a device is high, medium risk or low risk, depending on whether certain general risk criteria apply. Should all electrically powered devices used in any orifice be treated the same? Does a powered toothbrush pose the same level of risk as a resin tooth-bonding agent?

Industry Discussions Between the United States and Europe

Perspectives on Changing Risk Classification Systems

During a recent global medical device trade show in Cologne Germany, The Dental Manufacturers of America held several meetings to survey interest by EU, Japanese, Australian and Latin American industry on particular trade issues, including the risk classification approaches. Risk classification was a particular concern of small and medium sized businesses. As many dental products already enjoy less regulatory control under the FDA's device specific classification system, adopting it in Europe would reduce regulatory controls for many European manufacturers selling within their own economic region. In addition, Europeans would also benefit as device specific classification systems evolve with experience gained. Initial discussions with French Industry organizations, COMIDENT and SIFADENT, members indicated that they felt as if change to the European Medical Device Directive was unlikely if not impossible. One particular regulatory affairs representative from a French manufacturer explained his frustration when he tried to compel the EC to consider reviewing its risk classification of a particular product. He admitted that their rules-based system could not be altered without having a significant impact on a large number of other devices.

There are many incidences where medical devices would have their risk class adjusted upward or downward simply for the sake of harmonization (see page 4). The FDA is unable to adopt the GHTF's rules-based medical device risk classification system which contravenes the FDA's Modernization Act (FDAMA) enacted in 1998. FDAMA intended to reduce unnecessary regulatory burdens, not arbitrarily increase them. The GHTF's rule-based risk classification system does not lend itself to necessary changes in risk classifications. Risk classifications normally change over time as knowledge is gained. The FDA's current risk classifications are based on decades of experience. The newer rules-based approach also violates the FDA's mandate to protect the public by effectively regulating high risk devices. The GHTF proposal would adopt lower risk classifications for some devices the FDA believes to be high-risk. The GHTF proposal on risk classification is at odds with two key congressional mandates and discards years of hard work by U.S. scientists, government and industry. The FDA cannot and will not, adopt a rules-based system which is unhealthy for business and the citizens they are charged to protect

The Future of Global Medical Device Classifications

Changes to either the U.S. or EU systems for determining risk classification are either far off or improbable. The USDOC and FDA must work harder to address the needs of those in industry that make the majority of the world's medical devices. Industry representatives whose livelyhood comes from selling low or medium risk devices are rarely present at stakeholder meetings. These meetings have contributed little and threaten to have a negative impact on this medical device sector. Although the United States has been under significant pressure to adopt a rules-based approach to classifying these devices, this system does not provide the necessary oversight by qualified experts that the FDA has been able to provide. The rules-based approach also fails to promote *"continuous improvement" through "experience gained"*. Ironically this is the motto of the International Standards Organization (ISO) .

A Side-by-Side Comparison Chart of Medical Device Classifications

The Dental Manufacturers of America provided the first comparison between the European directive's rule-based medical device classification system and the FDA's Code of Federal Regulation Part 872 concerning dental equipment risk classifications. This side-by-side comparison showed that 37 of 124 devices classified by the FDA as low-risk were considered to be medium-risk by the European directive. Another 13 devices were considered higher risk by the FDA than the rule based system. The FDA is on record in regard to problems it has with using a rule-based system. "PMA's" are considered the slowest and most arduous process of placing high-risk and new technologies on the market.

GHTF

FDA Dental Devices List From 21 CFR 872	FDA Classification	European Classification
KEY Green rows represents a decrease in regulatory controls		
Subpart B - Diagnostic Devices		
872.1500 Gingival fluid measurer.	1	1
872.1720 Pulp tester.	2	2a
872.1730 Electrode gel for pulp tester.	1	1
872.1740 Caries detection device.	2	2
872.1800 Extraoral source x-ray system.	2	2b
872.1810 Intraoral source x-ray system.	2	2a
872.1820 Dental x-ray exposure alignment device.	1	1
872.1830 Cephalometer.	2	2a
872.1840 Dental x-ray position indicating device.		
872.1850 Lead-lined position indicator.		
872.1870 Sulfide detection device		
872.1905 Dental x-ray film holder.	1	1
Subpart C - [Reserved]		
Subpart D - Prosthetic Devices		
872.3050 Amalgam alloy.	2	2b
872.3060 Gold based alloys and precious metal alloys for clinical use.	2	2b
872.3080 Mercury and alloy dispenser.	1	1
872.3100 Dental amalgamator.	1	1
872.3110 Dental amalgam capsule.	1	1
872.3130 Preformed anchor.	1	1
872.3140 Resin applicator.	1	1
872.3150 Articulator.	1	1
872.3165 Precision attachment.		
872.3200 Resin tooth bonding agent.	2	2a
872.3240 Dental bur.		
872.3250 Calcium hydroxide cavity liner.	2	2b
872.3260 Cavity varnish.	2	2b
872.3275 Dental cement.	2	2b
872.3285 Preformed clasp.		
872.3300 Hydrophilic resin coating for dentures.	2	2a
872.3310 Coating material for resin fillings.	2	2b
872.3330 Preformed crown.		
872.3350 Gold or stainless steel cusp.		
872.3360 Preformed cusp.		
872.3400 Karaya and sodium borate with or without acacia denture adhesive.		
872.3410 Ethylene oxide homopolymer and/or carboxymethyl-cellulose sodium denture adhesive.		
872.3420 Carboxymethylcellulose sodium and cationic polyacrylamide polymer denture adhesive.	3	2a
872.3450 Ethylene oxide homopolymer and/or karaya denture adhesive.		
872.3480 Polyacrylamide polymer (modified cationic) denture adhesive.	3	2a
872.3490 Carboxymethylcellulose sodium and/or polyvinylmethylether maleic acid calcium-sodium double salt denture adhesive.		
872.3500 Polyvinylmethylether maleic anhydride (PVM-MA), acid copolymer, and carboxymethylcellulose sodium (NACMC) denture adhesive.	3	2a

For Reference Only

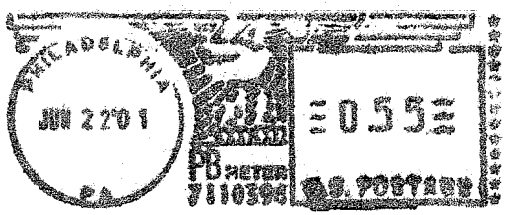
To obtain the entire three page chart, visit the DMA Website.
http://www.dmanews.org/dmaSection.cfm?sid=10

References

Industry Representatives Included:
Friedrich A. Herbst Executive Director International Dental Manufacturers Association (IDM) Representing European, American, Australian, Japanese and Latin American manufacturers.
Dierk Bellwinkel - General Secretary of EUROM 6 & Representative of the Federation of German Dental Industry (VDDI).
Jacques Mercier Delegated General of COMIDENT
COMIDENT represents three French dental organizations:
SIFADENT for the French dental industry,
UNIFAD Union of International Importers and Manufacturers for Dentistry, and
UDAD - Union of the Distributors for Dentistry.
Kathleen LaMar: Associate Director of the Dental Manufacturers of America (DMA)
Grant Ramaley: Associate Chairman, Regulatory Affairs and Technology Committee, (DMA)

Representatives from the United States included:
Edward Fantasia Commercial Director, U.S. Commercial Services, USDOC
Sylvia Mohr Standards Specialist, U.S. Mission to the EU, Foreign Commercial Service, USDOC.
Suzanne Radell Sene - Standards Attaché, U.S. Mission to the EU, Foreign Commercial Service, USDOC.

Additional input provided by:
John F. Stigi: FDA/CDRH Director of the Division of Small Manufacturers Assistance, and U.S. representative to the Joint Sectoral Committee of the Medical Device Annex of the U.S./EU Mutual Recognition Agreement.
Tim Ulatowski: director of FDA's Division of Dental, Infection Control, and General Hospital Devices and representative of the United States to the Global Harmonization Task Force Study Group 1.
Wright Investment Services -Industry Representative, Corporate Information
World Markets Research Center - Statistics on Medical Device Markets



FIRST CLASS MAIL

DENTAL MANUFACTURERS OF AMERICA, INC
FIDELITY BUILDING • SUITE 2030
123 SOUTH BROAD STREET
PHILADELPHIA, PA 19109-1020

TO:

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, rm. 1061
Rockville, MD 20852