U.S. Dental Industry Representative

Regulatory Affairs And Standards Committee

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Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Blvd., HFZ-480
Rockville, MD 20850UNITED STATES

RE: Comments concerning proposed the Global Harmonization Task Force guidance "Principles of Medical Devices Classification" **SG1 (PD)/N015**

Attn Deputy Director, Division of Anesthesiology, Gen. Hospital., Infection Control and Dental Devices.

Dear Dr. Michaud,

The Dental Trade Alliance has 200 members comprised of dental manufacturers and distributors located throughout the United States, Canada and many other parts of the world. The technologies provided by the dental industry treat the most prevalent forms of oral diseases worldwide. As a committed voice for the dental industry, we welcome this opportunity to comment on the Global Harmonization Task Force (GHTF) proposed document regarding risk classification SG1 (PD)/N015. The DTA closely watches GHTF activities and believes that risk classification proposals are among the most important, if not *the* most important of all proposals put forth by the GHTF. The DTA recognizes that in order to insure the safety and well-being of patients, all regulatory paths must begin with an accurate assessment of their risk. Though trade depends on effective harmonization, there are several aspects of SG1 (PD)/N015 that we feel will inhibit this proposal from being an acceptable tool for global harmonization.

1. The United States Cannot Adopt Risk Classification Rules into Law

The U.S. Food and Drug Administration (FDA) currently maintains risk classifications of nearly 5,000 specific devices. The application of GHTF risk rules would raise and lower these risk classifications and as a result would violate the intentions of the Food and Drug Administration Modernization Act (FDAMA) of 1997. Other longstanding congressional mandates concerning the protection of public health would also be challenged if any risk class were raised. The attached chart shows evidence that the 275 classified dental products regulated currently by the FDA would require 97 of them to be elevated above there assigned risk class 1, while 35 more would have to be down-classified to be harmonized with this proposal. The extent of impact on the other thousands of medical devices regulated by the FDA is not known, but is a cause of concern.

2. Device Specific Risk Classification Is Not Addressed Nor Plausible

The U.S. Dental industry has worked closely with the FDA and healthcare professionals to develop regulatory controls that more closely model the actual risk of dental products. As a result, since 1993, 40 dental products have been down-classified to low risk class 1. 68 devices have been dropped from 510(k) requirements and twenty one of these were exempted from Good Manufacturing Practice requirements. In comparison, since 1993, the inception date of the European Council Directive 93/42/EEC, not one medical device in Europe has been down-classified or elevated to a higher risk class. The European "Medical Device Expert Group", which is a consultive body for the European Union, reported in 2002 that reclassification was a concern that was among one of their "most critical concerns".

Adjusting risk classifications lower allows healthcare providers access to competing and sometimes entirely unique technologies. Assigning higher risk classifications is sometimes necessary to reduce of public exposure to devices found to be riskier than first thought.

As the risk rules of the European Directive indicate the historical shortcomings of the rules-based approach, it also acts as a forewarning against the use the GHTF proposal to use these same risk rules.

3. Generic Risk Rules Cannot Provide For Device Specific Risk Classification
GHTF and the aforementioned EU risk rules are known to be far too generic to be able to support changes in device specific risk classifications. As an example, the current European risk rule refers to a patient's ears, mouth, nose, eyes, anus, urethra, vagina, and even a surgically created stoma simply as "orifice". Attempting to make accommodations or restrictions for one device that operates in one orifice will therefore affect several device types used in other orifices. Consequently, changing the risk classification of a single device under the rules-based system is considerably more difficult, and has not occurred in Europe since the Medical Device Directive went into force.

4. Applying Risk Classifications to the Global Medical Device Nomenclature (GMDN)
The Dental Trade Alliance continues to promote the concept of including risk classifications in the Global Medical Device Nomenclature (GMDN) - ISO /TS 20225. The adoption of the FDA's Dental Product Codes into the existing ISO/TS 20225 without any major disruption shows how the DTA's proposed system has a viable and functional precedent. Where certain devices are currently unclassified by the FDA, and/or little post-market history exists, risk-rules could be used as guidance for assigning an initial risk classification. More importantly however, risk evaluation of post-market adverse event trends need to be able to affect more relevant risk classification assignments. This combination approach would include using risk rules, only where no such historical trends exists.

5. Evidence Shows That Risk Rules Are Too Confusing For Industry and Regulators
The DTA's Regulatory Affairs and Standards Committee often fields questions from dental industry members who are trying to interpret and apply the risk-rules in Annex IX of 93/42/EEC. It is a direct result of the confusion created by these rules that the European Commission created a two-part Medical Device Guidance Document (MEDDEV 2.4/1 – GUIDELINE FOR THE CLASSIFICATION OF MEDICAL DEVICES) to rectify the situation. This guidance document, 43 pages long, and broken into two parts, was needed to allay the confusion created by the original nine-pages in Annex IX of 93/42/EEC. The GHTF proposal is little more than an adoption of the MEDDEV document 2.4/1.

A sample from the GHTF **SG1 (PD)/N015** and **MEDDEV 2.4/1** are shown below and on the next page for comparison purposes.

SG1 (PD)/N015 Principles of Medical Devices Classification

RULE	ILLUSTRATIVE EXAMPLES OF DEVICES THAT MAY CONFORM WITH A RULE
➢ ***NON-INVASIVE DEVICES***	
1. All non-invasive devices are in Class A, unless Rule 2, 3 or 4 applies.	These devices either do not touch the patient or contact intact skin only. Examples: urine collection bottles; compression hosiery; non-invasive electrodes, hospital beds. **NOTE:** Non-invasive devices that are indirectly in contact with the body & can influence internal physiological processes by storing, channeling or treating blood, other body liquids or liquids which are returned or infused into the body or by generating energy that is delivered to the body are outside the scope of this rule.

GUIDELINES FOR THE CLASSIFICATION OF MEDICAL DEVICES MEDDEV 2.4/1

RULE	Example
All non-invasive devices are in Class I, unless one of the rules set out hereinafter applies.	- Body liquid collection devices intended to be used in such a way that a return flow is unlikely (e.g. to collect body wastes such as urine collection bottles, ostomy pouches, incontinence pads or collectors used with wound drainage devices). They may be connected to the patient by means of catheters and tubing. - Devices used to immobilize body parts and/or to apply force or compression on them (e.g. non-sterile dressings used to aid the healing of a sprain, plaster of Paris, cervical collars, gravity traction devices, compression hosiery). - Devices intended in general for external patient support (e.g. hospital beds, patient hoists, walking aids, wheelchairs, stretchers, dental patient chairs). - Corrective glasses, frames, stethoscopes for diagnosis, eye occlusion plasters, incision drapes, conductive gels, non-invasive electrodes (electrodes for EEG or ECG), image intensifying screens. - Permanent magnets for removal of ocular debris

Both documents make an attempt to explain how risk rules apply to specific devices by giving examples of some of the device types. This, of course, is quite helpful, however, unless your business is making or selling urine collection bottles, or one of the other few device types mentioned, the guidance falls well short of the nearly 5,000 specific medical device types currently regulated by the FDA and listed in the Global Medical Device Nomenclature.

6. Small Business and Dental Industry Concerns

It is very important to note that smaller manufactures, which are well understood to make up 70% to 80% of the medical device manufacturers worldwide, need more help from regulators than larger companies. The FDA originally created the Division of Small Manufacturers Assistance (DSMA) for this very reason. Although the DSMA now offers international and consumer assistance as well, (DSMICA) staff feel they best serve companies with 50 or fewer employees. There is no medical device industry sector that more aptly fits the description of what the FDA considers needful of assistance than the dental device industry. Nonetheless, nearly all oral healthcare systems worldwide are dependent on dental device manufacturers and the distributors who sell their products. The Dental Manufacturers of America (DMA), in their most recent report, indicate that nearly half of dental manufacturers have fewer than 50 employees and have gross sales near 10 million dollars annually. This is $1/10^{th}$ the size needed to qualify as a small business under the Medical Device User Fee Modernization Act (MDFUMA). Smaller companies have fewer resources to insure compliance and any change in risk classification that elevates compliance requirements would result in reduced access to technologies needed by dental professionals. There is no better example of how badly this can affect an oral healthcare system than the current situation in Canada.

A Very Real Adverse Impact on Oral Healthcare Systems

Canadian dentists are now finding that many devices that are classified as low risk in the United States are considered class II and therefore illegal in Canada unless they have a special class II or III medical device licence. Health Canada's new guidance on risk classification (enforced since 2001) has made the regulatory burden too costly for many small dental companies. For most small manufacturers, the cost of Canadian compliance outweighs the benefits of selling into Canada. As such, the standard of healthcare in Canada continues to struggle against Health

Canada's new Medical Device Regulations. Whole categories of medical device types are absent from Health Canada's MDALL database www.mdall.ca, which lists all legally available medical devices that are higher than risk class I. In response to this crisis Health Canada has recently implement a new "Special Access" program to allow healthcare professionals to file a petition with Health Canada to explain why they should be allowed to purchase what the doctor feels is a medically necessary device that is unlicensed.

With the new global approach to medical device regulations focusing increasing attention on precise control of risk through good monitoring and analysis of post-market activities; it makes good sense to incorporate these same principles into an effective risk classification system.

Looking for a simple solution to the complex problem of assessing the risk of medical devices only creates new problems, and in this case, clearly threatens healthcare systems that are looking to the GHTF for solutions. The Dental Trade Alliance supports principles of risk classification that include provisions for assigning risk classes to specific devices and then allow for adjusting these risk classes after a preponderance of evidence is collected through clearly controlled monitoring measuring and analysis activities.

The Dental Trade Alliance welcomes the efforts to harmonize medical device regulations worldwide. Much of the work done by the GHTF has been extremely helpful and we continue to promote many of the recommendations of the GHTF to our members.

If I can be of any further assistance, I am pleased to offer any service I can.

Sincerely Yours,

Grant Ramaley
Chairman
Regulatory Affairs and Standards Committee
Dental Trade Alliance

ATTACHMENT: Dental Product Code Risk Classification Chart

The attached is a useful tool for determining how risk classifications vary between the FDA and the GHTF/EU application of risk rules. The DTA examined all 294 dental products classified by the FDA, including 18 unclassified dental products. Four of the unclassified devices have recently been an assigned a proposed medium "risk class 2" by the FDA's Dental Products Panel.

Based on GHTF Proposed Risk Rules From SG1 (PD)/N015 and European Council Directive 93/42/EEC Annex IX.

Green and Red highlights indicate a change to either higher or lower risk classification than those currently established by the FDA Product Codes and supporting regulations under 21 CFR Part 872.

Chart Legend Color Codes
Increase in risk class from FDA risk class
Decrease in risk class from FDA risk class

Dental Device Risk Classification Chart

Device Category Name (FDA Product Code Name)	FDA Regulation #	FDA Product Code	Risk Class Comparisons			GHTF & MDD Risk Rule
			FDA	GHTF	MDD	Rule #
Measurer, gingival fluid	872.1500	JEO	1	A	1	Rule 5
Tester, pulp	872.1720	EAT	2	B	2a	Rule 10
Gel, electrode, for pulp tester	872.1730	EAS	1	B	2a	Rule 5
Device, caries detection	872.1740	LFC	2	A	1	Rule 5
Laser,fluorescence caries detection	872.1745	NBL	2	A	1	Rule 12
Caries detector, laser light, transmission	872.1745	NTK	2	A	1	Rule 12
Unit, x-ray, extraoral with timer	872.1800	EHD	2	C	2b	Rule 10
System,x-ray,extraoral source,digital	872.1800	MUH	2	C	2b	Rule 10
Unit, x-ray, intraoral	872.1810	EAP	2	C	2b	Rule 10
Aligner, beam, x-ray	872.1820	EHA	1	A	1	Rule 10
Cephalometer	872.1830	EAG	2	C	2b	Rule 10
Collimator, x-ray	872.1840	EHB	1	C	2b	Rule 10
Cone, radiographic, lead-lined	872.1850	EAH	1	C	2b	Rule 10
Device, detection, sulfide	872.1870	MVH	2	B	2a	Rule 10
Holder, film, x-ray	872.1905	EGZ	1	B	2a	Rule 16 - MDD only
Device, dental sonography, for diagnosis of tmj/mpd disorders	872.2050	NFP	2	B	2a	Rule 10
Device, dental sonography, for monitoring jaw sounds	872.2050	NFQ	1	B	2a	Rule 10
Device, jaw tracking, for diagnosis of tmj/mpd disorders	872.2060	NFR	2	B	2a	Rule 10
Device, jaw tracking, for monitoring jaw positions	872.2060	NFS	1	B	2a	Rule 10
Alloy, amalgam	872.3050	EJJ	2	B	2a	Rule 8
Applicator, rapid wax, dental	872.3060	EIT	2	B	2a	Rule 8
Alloy, other noble metal	872.3060	EJS	2	B	2a	Rule 8
Alloy, gold-based noble metal	872.3060	EJT	2	B	2a	Rule 8
Dispenser, mercury and/or alloy	872.3080	EHE	1	A	1	Rule 12
Amalgamator, dental, ac-powered	872.3100	EFD	1	A	1	Rule 1
Capsule, dental, amalgam	872.3110	DZS	1	B	2a	Rule 8
Anchor, preformed	872.3130	EJX	1	B	2a	Rule 8
Applicator, resin	872.3140	KXR	1	A	1	Rule 5
Articulators	872.3150	EJP	1	A	1	Rule 1
Ink, arch tracing	872.3150	KZO	1	A	1	Rule 1
Attachment, precision, all	872.3165	EGG	1	A	2a	Rule 5
Bar, preformed	872.3165	EHO	1	A	2a	Rule 5
Agent, tooth bonding, resin	872.3200	KLE	2	B	2A	Rule 8
Facebow	872.3220	KCR	1	A	1	Rule 5
Bur, dental	872.3240	EJL	1	B	2a	Rule 6
Bur, diamond coated, reprocessed	872.3240	NME	1	B	2a	Rule 6
Liner, cavity, calcium hydroxide	872.3250	EJK	2	D	3	Rule 13
Varnish, cavity	872.3260	LBH	2	B	2a	Rule 8
Cement, dental	872.3275	EMA	2	B	2a	Rule 8
Dental cement w/ zinc oxide eugenol	872.3275	EMB	1	B	2a	Rule 7
Dental cement w/out zinc-oxide eugenol as an ulcer covering for pain relief	872.3275	MZW	2	A	2a	Rule 8
Cement, ear, nose and throat	872.3275	NEA	2	B	2a	Rule 8
Clasp, preformed	872.3285	EHP	1	A	1	Rule 5
Clasp, wire	872.3285	EJW	1	A	1	Rule 5

Dental Device Risk Classification Chart

Device Category Name (FDA Product Code Name)	FDA Regulation #	FDA Product Code	Risk Class Comparisons			GHTF & MDD Risk Rule
			FDA	GHTF	MDD	Rule #
Coating, denture hydrophilic, resin	872.3300	EBE	2	A	1	Rule 5
Coating, filling material, resin	872.3310	EBD	2	B	2a	Rule 5
Crown, preformed	872.3330	ELZ	1	B	2a	Rule 7
Cusp, gold and stainless steel	872.3350	ELO	1	B	2a	Rule 7
Cusp, preformed	872.3360	EHQ	1	B	2a	Rule 5
Adhesive, denture, acacia and karaya with sodium borate	872.3400	KOM	1	A	1	Rule 5
Adhesive, denture, karaya with sodium borate	872.3400	KOR	3	D	3	Rule 13
Adhesive, denture, acacia and karaya with sodium borate > 12% by weight	872.3400	MMU	3	D	3	Rule 13
Adhesive, denture, carboxymethylcellulose sodium (32%) and ethylene-oxide homopolymer	872.3410	KOL	1	A	1	Rule 5
Adhesive, denture, carboxymethylcellulose sodium (40-100&)	872.3410	KOQ	1	A	1	Rule 5
Adhesive, denture, carboxymethylcellulose sodium (49%) and ethylene-oxide homopolymer	872.3410	KXW	1	A	1	Rule 5
Adhesive, denture, carboxymethylcellulose sodium and cationic polyacrylamide polymer	872.3420	KOS	3	A	1	Rule 5
Adhesive, denture, karaya	872.3450	KOP	1	A	1	Rule 5
Adhesive, denture, karaya and ethylene-oxide homopolymer	872.3450	KXX	1	A	1	Rule 5
Adhesive, denture, polyacrylamide polymer (modified cationic)	872.3480	KON	3	A	1	Rule 5
Adhesive, denture, polyvinyl methylether maleic acid calcium-sodium double salt	872.3490	KOO	1	A	1	Rule 5
Carboxymethylcellulose sodium or polyvinyl methylether maleic acid calcium-sodium	872.3490	KOT	1	A	1	Rule 5
Polyvinyl methylether maleic anhydride &/or acid copolymer & carboxymethylce	872.3500	KXY	3	A	1	Rule 5
Cleanser, denture, over the counter	872.3520	EFT	1	A	1	Rule 1
Cleanser, denture, prescription	872.3520	NUX	1	A	1	Rule 1
Cleaner, denture, mechanical	872.3530	JER	1	A	1	Rule 1
Cad, denture, over the counter	872.3540	EHR	2	A	1	Rule 5
Cushion, denture, over the counter	872.3540	EHS	2	A	1	Rule 5
Cushion, pad, denture, wax impregnated cotton, over the Counter	872.3540	NKJ	1	A	1	Rule 5
Reliner, denture, over the counter	872.3560	EBP	2	A	1	Rule 5
Kit, denture repair, over the counter	872.3570	EBO	2	A	1	Rule 5
Teeth, preformed gold denture	872.3580	ELN	1	A	1	Rule 5
Denture, plastic, teeth	872.3590	ELM	2	A	1	Rule 5
Denture preformed (partially prefabricated denture)	872.3600	EKO	2	A	1	Rule 5
Abutment, implant, dental, endosseous	872.3630	NHA	2	C	2b	Rule 8
Implant, endosseous, root-form	872.3640	DZE	2	C	2b	Rule 8
Blade-form endosseous dental implant	872.3640	NRQ	3	C	2b	Rule 8
Implant, subperiosteal	872.3645	ELE	2	C	2b	Rule 8
Material, impression	872.3660	ELW	2	A	1	Rule 5

Dental Device Risk Classification Chart

Device Category Name (FDA Product Code Name)	FDA Regulation #	FDA Product Code	Risk Class Comparisons			GHTF & MDD Risk Rule
			FDA	GHTF	MDD	Rule #
Scanner, color	872.3661	KZN	2	A	1	Rule 1
System, optical impression, computer assisted design and manufacturing (cad/cam) of dental restorations	872.3661	NOF	2	A	1	Rule
Material, impression tray, resin	872.3670	EBH	1	A	1	Rule 5
Materials, polytetrafluoroethylene vitreous carbon, for maxillofacial alveolar ridge augmentation	872.3680	NFE	2	C	2b	Rule 8
Material, tooth shade, resin	872.3690	EBF	2	B	2a	Rule 8
mercury	872.3700	ELY	1	B	2a	Rule 8
Alloy, metal, base	872.3710	EJH	2	B	2a	Rule 8
Pantograph	872.3730	KCS	1	A	1	Rule 5
Pin, retentive and splinting, and access	872.3740	EBL	1	B	2a	Rule 8
Adhesive, bracket and tooth conditioner,	872.3750	DYH	2	B	2a	Rule 5
Solution, cement disolving	872.3750	KZP	2	A	1	Rule 5
Resin, denture, relining, repairing, reb	872.3760	EBI	2	A	1	Rule 5
Sealant, pit and fissure, and conditione	872.3765	EBC	2	B	2a	Rule 5
Crown and bridge, temporary, resin	872.3770	EBG	2	A	1	Rule 5
Post, root canal	872.3810	ELR	1	B	2a	Rule 8
Resin, root canal filling	872.3820	KIF	2	B	2a	Rule 8
Resin, root canal filling containing chloroform	872.3820	MMT	3	B	2a	Rule 8
Point, paper, endodontic	872.3830	EKN	1	A	2a	Rule 6
Point, silver, endodontic	872.3840	EKL	1	B	2a	Rule 8
Gutta-percha	872.3850	EKM	1	B	2a	Rule 8
Splint, endodontic stabilizing	872.3890	ELS	2	C	2b	Rule 8
Teeth, artificial, posterior with metal	872.3900	ELJ	1	B	2a	Rule 5
Teeth, artificial, backing and facing	872.3910	ELK	1	B	2a	Rule 5
Teeth, porcelain	872.3920	ELL	2	B	2a	Rule 5
Bone grafting material, for dental bone	872.3930	LPK	2	C	2b	Rule 8
Bone grafting material, synthetic	872.3930	LYC	2	C	2b	Rule 8
Bone grafting material, animal source	872.3930	NPM	2	C	2b	Rule 8
Bone grafting material, dental, with bio	872.3930	NPZ	3	D	3	Rule 13
Biologic material, dental	872.3930	NQA	3	D	3	Rule 13
Bone grafting material, human source	872.3930	NUN	2	C	2b	Rule 8
Joint, temporomandibular, implant	872.3940	LZD	3	C	2b	Rule 8
Glenoid fossa prosthesis	872.3950	MPI	3	C	2b	Rule 8
Manidbular condyle prosthesis	872.3960	MPL	3	C	2b	Rule 8
Prosthesis, condyle, mandibular, temporary	872.3960	NEI	3	C	2b	Rule 8
Interarticular disc prosthesis (interpositional implant)	872.3970	MPJ	3	C	2b	Rule 8
Accessories, implant, dental, endosseous	872.3980	NDP	1	A	1	Rule 5
Saw, bone, ac-powered	872.4120	DZH	2	B	2a	Rule 9
Drill, bone, powered	872.4120	DZI	2	B	2a	Rule 9
Driver, wire, and bone drill, manual	872.4120	DZJ	2	B	2a	Rule 9
Handpiece, rotary bone cutting	872.4120	KMW	2	B	2a	Rule 9
System,dental,hydrokinetic,carries remov	872.4120	MXF	2	B	2a	Rule 9
Drill, dental, intraoral	872.4130	DZA	1	B	2a	Rule 9
Controller, foot, handpiece and cord	872.4200	EBW	1	B	2a	Rule 9
Handpiece, belt and/or gear driven, dental	872.4200	EFA	1	B	2a	Rule 9

Dental Device Risk Classification Chart

Device Category Name (FDA Product Code Name)	FDA Regulation #	FDA Product Code	Risk Class Comparisons			GHTF & MDD Risk Rule
			FDA	GHTF	MDD	Rule #
Handpiece, air-powered, dental	872.4200	EFB	1	B	2a	Rule 9
Handpiece, contra- and right-angle attachment, dental	872.4200	EGS	1	B	2a	Rule 9
Handpiece, direct drive, ac-powered	872.4200	EKX	1	B	2a	Rule 9
Handpiece, water-powered	872.4200	EKY	1	B	2a	Rule 9
Injector, jet, gas-powered	872.4465	EGQ	2	B	2a	Rule 9
Injector, jet, mechanical-powered	872.4475	EGM	2	B	2a	Rule 6
Instrument, diamond, dental	872.4535	DZP	1	B	2a	Rule 6
Instrument, diamond, dental, reprocessed	872.4535	NLD	1	B	2a	Rule 6
Instruments, dental hand	872.4565	DZN	1	A	1	Rule 5
Mirror, mouth	872.4565	EAX	1	A	1	Rule 5
Unit, syringe, air and/or water	872.4565	ECB	1	B	2a	Rule 11
Instrument, ligature tucking, orthodontic	872.4565	ECP	1	A	1	Rule 5
Aligner, bracket, orthodontic	872.4565	ECQ	1	A	1	Rule 5
Setter, band, orthodontic	872.4565	ECR	1	A	1	Rule 5
Pusher, band, orthodontic	872.4565	ECS	1	A	1	Rule 5
Driver, band, orthodontic	872.4565	ECT	1	A	1	Rule 5
Forceps, articulation paper	872.4565	EFK	1	A	1	Rule 5
Forceps, dressing, dental	872.4565	EFL	1	A	1	Rule 5
Parallelometer	872.4565	EGI	1	A	1	Rule 5
Scissors, surgical tissue, dental	872.4565	EGN	1	B	2a	Rule 6
Syringe, irrigating (dental)	872.4565	EIB	1	B	2a	Rule 11
Syringe, periodontic, endodontic, irrigating	872.4565	EIC	1	B	2a	Rule 11
Syringe, restorative and impression mate	872.4565	EID	1	B	2a	Rule 11
Accessories, retractor, dental	872.4565	EIF	1	A	1	Rule 5
Retractor, all types	872.4565	EIG	1	A	1	Rule 5
Carver, wax, dental	872.4565	EIK	1	A	1	Rule 5
Gauge, depth, instrument, dental	872.4565	EIL	1	B	2a	Rule 6
Scissors, collar and crown	872.4565	EIR	1	A	1	Rule 1
Remover, crown	872.4565	EIS	1	A	1	Rule 5
Probe, periodontic	872.4565	EIX	1	A	1	Rule 5
Instrument, filling, plastic, dental	872.4565	EIY	1	A	1	Rule 5
Handle, instrument, dental	872.4565	EJB	1	A	1	Rule 1
Pliers, operative	872.4565	EJY	1	A	1	Rule 5
Knife, margin finishing, operative	872.4565	EJZ	1	A	1	Rule 5
File, margin finishing, operative	872.4565	EKA	1	A	1	Rule 5
Explorer, operative	872.4565	EKB	1	A	1	Rule 5
Excavator, dental, operative	872.4565	EKC	1	B	2a	Rule 6
Instrument, cutting, operative	872.4565	EKD	1	B	2a	Rule 6
Curette, operative	872.4565	EKE	1	B	2a	Rule 6
Instrument, contouring, matrix, operative	872.4565	EKF	1	A	1	Rule 5
Condenser, amalgam and foil, operative	872.4565	EKG	1	A	1	Rule 5
Carver, dental amalgam, operative	872.4565	EKH	1	A	1	Rule 5
Carrier, amalgam, operative	872.4565	EKI	1	A	1	Rule 5
Burnisher, operative	872.4565	EKJ	1	A	1	Rule 5
Spreader, pulp canal filling material, endodontic	872.4565	EKK	1	B	2a	Rule 6
Reamer, pulp canal, endodontic	872.4565	EKP	1	B	2a	Rule 6
Reparer, root canal endodontic	872.4565	EKQ	1	B	2a	Rule 6

Dental Trade Alliance
Regulatory Affairs and Standards Committee
February 2nd 2006

For Guidance Purposes Only

Dental Device Risk Classification Chart

Device Category Name (FDA Product Code Name)	FDA Regulation #	FDA Product Code	Risk Class Comparisons			GHTF & MDD Risk Rule
			FDA	GHTF	MDD	Rule #
Plugger, root canal, endodontic	872.4565	EKR	1	B	2a	Rule 6
File, pulp canal, endodontic	872.4565	EKS	1	B	2a	Rule 6
Curette, endodontic	872.4565	EKT	1	B	2a	Rule 6
Broach, endodontic	872.4565	EKW	1	B	2a	Rule 6
Instrument, hand, calculus removal	872.4565	ELA	1	B	2a	Rule 6
Hemostat, surgical	872.4565	EMD	1	A	1	Rule 5
Punch, biopsy, surgical	872.4565	EME	1	B	2a	Rule 6
Forceps, tooth extractor, surgical	872.4565	EMG	1	B	2a	Rule 6
Forceps, rongeur, surgical	872.4565	EMH	1	B	2a	Rule 6
File, bone, surgical	872.4565	EMI	1	B	2a	Rule 6
Elevator, surgical, dental	872.4565	EMJ	1	B	2a	Rule 6
Curette, surgical, dental	872.4565	EMK	1	B	2a	Rule 6
Chisel, bone, surgical	872.4565	EML	1	B	2a	Rule 6
Chisel, osteotome, surgical	872.4565	EMM	1	B	2a	Rule 6
Scaler, periodontic	872.4565	EMN	1	B	2a	Rule 6
Knife, periodontic	872.4565	EMO	1	B	2a	Rule 6
Marker, periodontic	872.4565	EMP	1	B	2a	Rule 6
Hoe, periodontic	872.4565	EMQ	1	B	2a	Rule 6
File, periodontic	872.4565	EMR	1	B	2a	Rule 6
Curette, periodontic	872.4565	EMS	1	B	2a	Rule 6
Retainer, matrix	872.4565	JEP	1	A	1	Rule 5
Plier, orthodontic	872.4565	JEX	1	A	1	Rule 5
Lock, wire, and ligature, intraoral	872.4600	DYX	2	A	1	Rule 5
Light, fiber optic, dental	872.4620	EAY	1	A	1	Rule 12
Light, operating, dental	872.4630	EAZ	1	A	1	Rule 12
Light, surgical headlight	872.4630	EBA	1	A	1	Rule 12
Needle, dental	872.4730	DZM	1	B	2a	Rule 6
Needle, dental, reprocessed	872.4730	NMW	1	B	2a	Rule 6
Plate, bone	872.4760	JEY	2	C	2b	Rule 8
Implant, transmandibular	872.4760	MDL	2	C	2b	Rule 8
External mandibular fixator and/or distractor	872.4760	MQN	2	C	2b	Rule 8
Scaler, rotary	872.4840	ELB	2	B	2a	Rule 9
Scaler, ultrasonic	872.4850	ELC	2	B	2a	Rule 9
Wire, fixation, intraosseous	872.4880	DZK	2	C	2b	Rule 8
Screw, fixation, intraosseous	872.4880	DZL	2	C	2b	Rule 8
Unit, electrosurgical, and accessories,	872.4920	EKZ	2	C	2b	Rule 9
Retainer, screw expansion, orthodontic	872.5410	DYJ	1	B	2a	Rule 5
Band, material, orthodontic	872.5410	DYO	1	B	2a	Rule 5
Wire, orthodontic	872.5410	DZC	1	B	2a	Rule 5
Tube, orthodontic	872.5410	DZD	1	B	2a	Rule 5
Band, elastic, orthodontic	872.5410	ECI	1	B	2a	Rule 5
Band, preformed, orthodontic	872.5410	ECM	1	B	2a	Rule 5
Clamp, wire, orthodontic	872.5410	ECN	1	B	2a	Rule 5
Spring, orthodontic	872.5410	ECO	1	B	2a	Rule 5
Bracket, metal, orthodontic	872.5410	EJF	1	B	2a	Rule 5
Bracket, metal, orthodontic, reprocessed	872.5410	NQS	1	B	2a	Rule 5
Bracket, plastic, orthodontic	872.5470	DYW	2	B	2a	Rule 5
Bracket, ceramic, orthodontic	872.5470	NJM	2	B	2a	Rule 5
Bracket, plastic, orthodontic, reprocess	872.5470	NLC	2	B	2a	Rule 5

Dental Device Risk Classification Chart

Device Category Name (FDA Product Code Name)	FDA Regulation #	FDA Product Code	Risk Class Comparisons			GHTF & MDD Risk Rule
			FDA	GHTF	MDD	Rule #
Headgear, extraoral, orthodontic	872.5500	DZB	2	A	1	Rule 1
Maintainer, space preformed, orthodontic	872.5525	DYT	1	B	2a	Rule 5
Positioner, tooth, preformed	872.5525	KMY	1	B	2a	Rule 5
Ring, teething, fluid-filled	872.5550	KKO	2	A	1	Rule 5
Ring, teething, non-fluid filled	872.5550	MEF	1	A	1	Rule 5
Device, jaw repositioning	872.5570	LQZ	2	B	2a	Rule 5
Device, anti-snoring	872.5570	LRK	2	B	2a	Rule 5
Pillow,cervical(for mild sleep apnea)	872.5570	MYB	2	A	1	Rule 1
Rinse, oral, antibacterial (by physical means)	872.5580	NTO	2	A	1	Rule 5
guard, disk	872.6010	EEJ	1	A	1	Rule 5
Disk, abrasive	872.6010	EHJ	1	B	2a	Rule 9
Point, abrasive	872.6010	EHL	1	B	2a	Rule 9
Strip, polishing agent	872.6010	EHM	1	B	2a	Rule 9
Wheel, polishing agent	872.6010	EJQ	1	B	2a	Rule 9
Agent, polishing, abrasive, oral cavity	872.6030	EJR	1	A	1	Rule 5
Cotton, roll	872.6050	EFN	1	A	1	Rule 5
Absorber, saliva, paper	872.6050	KHR	1	A	1	Rule 5
Activator, ultraviolet, for polymerization	872.6070	EBZ	2	A	1	Rule 12
Airbrush	872.6080	KOJ	2	B	2a	Rule 9
Warmer, anesthetic tube	872.6100	EFC	1	A	1	Rule 1
Paper, articulation	872.6140	EFH	1	A	1	Rule 5
Plate, base, shellac	872.6200	EEA	1	A	1	Rule 5
Chair, dental, with operative unit	872.6250	KLC	1	B	2a	Rule 9
Chair, dental, without operative unit	872.6250	NRU	1	A	1	Rule 12
Cup, prophylaxis	872.6290	EHK	1	B	2a	Rule 9
Clamp, rubber dam	872.6300	EEF	1	A	1	Rule 5
Dam, rubber	872.6300	EIE	1	A	1	Rule 5
Frame, rubber dam	872.6300	EJE	1	A	1	Rule 1
Forceps, rubber dam clamp	872.6300	EJG	1	A	1	Rule 5
Detector, ultraviolet	872.6350	EAQ	2	A	1	Rule 12
Floss, dental	872.6390	JES	1	A	1	Rule 1
Heat source for bleaching teeth	872.6475	EEG	1	B	2a	Rule 9
Unit, oral irrigation	872.6510	EFS	1	B	2a	Rule 11
Tube impression and matrix	872.6570	KCQ	1	A	1	Rule 5
Mouthpiece, saliva ejector	872.6640	DYN	1	B	2a	Rule 11
Unit, suction operatory	872.6640	EBR	1	B	2a	Rule 11
Evacuator, oral cavity	872.6640	EHZ	1	B	2a	Rule 11
Unit, operative dental	872.6640	EIA	1	B	2a	Rule 9
Unit, operative dental, accessories	872.6640	NRD	1	B	2a	Rule 9
Pick, massaging	872.6650	JET	1	A	1	Rule 5
Tip, rubber, oral hygiene	872.6650	JEW	1	A	1	Rule 5
Powder, porcelain	872.6660	EIH	2	B	2a	Rule 5
Protector, silicate	872.6670	EFX	1	B	2a	Rule 5
Sterilizer, boiling water	872.6710	ECG	1	B	2a	Rule 15
Sterilizer, glass bead	872.6730	ECC	3	B	2a	Rule 15
Sterilizer, endodontic dry heat	872.6730	KOK	3	B	2a	Rule 15
Syringe, cartridge	872.6770	EJI	2	A	1	Rule 2
Toothbrush, manual	872.6855	EFW	1	A	1	Rule 5
Scraper, tongue	872.6855	LCN	1	A	1	Rule 5

Dental Device Risk Classification Chart

Device Category Name (FDA Product Code Name)	FDA Regulation #	FDA Product Code	Risk Class Comparisons			GHTF & MDD Risk Rule
			FDA	GHTF	MDD	Rule #
Eraser, dental stain	872.6855	MAU	1	A	1	Rule 5
Unit, ultraviolet sanitation/sterilization (for toothbrushes), sterile	872.6855	MCF	1	B	2a	Rule 15
Unit, ultraviolet sanitation/sterilization (for toothbrushes), non-sterile	872.6855	NOB	1	B	2a	Rule 15
Toothbrush, powered	872.6865	JEQ	1	B	2a	Rule 9
Toothbrush, ionic, battery-powered	872.6865	MMD	1	B	2a	Rule 9
Tray, fluoride, disposable	872.6870	KMT	1	A	1	Rule 5
Tray, impression, preformed	872.6880	EHY	1	A	1	Rule 5
Wax, dental, intraoral	872.6890	EGD	1	A	1	Rule 5
FDA UNCLASSIFIED DEVICE as of January 2006						
Device, electrical dental anesthesia	Pending	LWM	*2	B	2a	Rule 9
Device, finger-sucking	Pending	LQX	Un	A	1	Rule 5
Locator, root apex	Pending	LQY	*2	B	2a	Rule 9
Barrier, synthetic, dental	Pending	NPK	Un	D	3	Rule 8
Barrier, animal source, dental	Pending	NPL	Un	D	3	Rule 8
Restoration, noble metal	Pending	NSJ	Un	B	2a	Rule 8
Dentures, partial	Pending	NSK	Un	A	1	Rule 5
Dentures, full	Pending	NSL	Un	A	1	Rule 5
Restoration, resin	Pending	NSM	Un	A	1	Rule 5
Restoration, resin, crown and bridge	Pending	NSN	Un	B	2a	Rule 7
Restoration, porcelain-fused-to-metal	Pending	NSO	Un	B	2a	Rule 7
Restoration, porcelain	Pending	NSP	Un	B	2a	Rule 7
Restoration, base metal	Pending	NSQ	Un	B	2a	Rule 7
Prosthesis, orthodontic	Pending	NSR	Un	B	2a	Rule 7
Mouthguard	Pending	MQC	*2	A	1	Rule 5
Material, investment	Pending	EGC	Un	A	1	Rule 1
Cleanser, root canal	Pending	KJJ	Un	D	3	Rule 13
Cord, retraction	Pending	MVL	*2	A or D	1 or 3	Rule 5 or Rule 13
Saliva, artificial	Pending	LFD	Un	D	3	Rule 13

LEGEND	
GHTF and EU Risk Classes Are Lower than FDA	
GHTF and EU Risk Classes Are Higher than FDA	
	Dental Panel Meeting Proposed Risk Class