

117 04 MAY 25 21 42



May 18, 2004

Ginette Michaud
Study Group I
Global Harmonization Task Force
Dockets Management
HFA-305
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, Maryland 20852

Re: Docket No. 2004D-0001

Dear Ms. Michaud:

This comment is filed on behalf of the Cook Group, Inc. ("Cook"), a holding company of international corporations engaged in the manufacture of diagnostic and interventional products for radiology, cardiology, urology, gynecology, gastroenterology, emergency medicine, and surgery. Cook pioneered the development of products used in the Seldinger technique of angiography, and in techniques for interventional radiology and cardiology. Cook products benefit patients by providing doctors with a means of diagnosis and intervention without the necessity of invasive surgery. Cook sells over 15,000 different products which can be purchased in over 60,000 combinations.

We are submitting these comments in response to the request of the Food and Drug Administration (FDA) for comments regarding documents that were prepared by the Global Harmonization Task Force (GHTF). Our comments are directed specifically to the proposed document entitled, "Principles of Medical Device Classification" prepared by Study Group I of the GHTF.

We are very grateful for the opportunity to submit our views. Cook wishes to commend the GHTF and its members for the important and difficult work it has performed over the last dozen years. We applaud the GHTF's recognition that proper medical technology regulation is a global issue.

750 Daniels Way
Bloomington, IN 47402
www.cookgroupinc.com

2004D-0001

C 1

Ms. Ginette Michaud
May 18, 2004
Page Two

We have several observations regarding "Principles of Medical Device Classification," but first would like to note the difficulty in making definitive statements without knowing what regulatory requirements will apply to the various classes set forth in the document. We recognize that the paper on "Principles of Conformity Assessment for Medical Devices" is currently under development and will be available for public comment. We believe that it is critical that these two documents be reviewed in concert with one another. We recommend that the GHTF solicit additional comments on the classification document when it publishes and requests comments on the conformity assessment document. Stakeholders should have the ability to submit additional comments on the classification document at that time.

For purposes of these comments, Cook assumes that a classification system is being developed to be reflective of the risks associated with various types of devices. The regulatory requirements would become more rigorous as the class increases from Class A to Class D.

After reviewing the initial classification rules, it appears that the proposed system is too rigid and would over classify many products. The rules do not recognize that experience with a particular device will often reduce the level of risk associated with the device. In tandem with the least burdensome approach to device regulation being developed by the FDA, it is important that the evolving GHTF classification scheme reflect not only the degree of risk posed by a medical device, but also take into consideration the least burdensome means for manufacturers to comply with regulatory requirements. Underlying the least burdensome approach is a tacit recognition that experience, by necessity, reduces risk.

For example, the first embolization devices were novel products and required careful scrutiny. Clinical experience and successful clinical use has increased regulators' familiarity with these products, and they are in the process of being downclassified from class III to class II by the FDA. The proposed GHTF classification rules, however, would automatically classify any product intended for use in the central circulatory system, even inactive products used to diagnose or monitor, as Class D products. In addition to the embolization devices, this would include virtually all catheters, wireguides, dilators, etc., used in the central circulatory system which are Class II products in the United States, subject to review under section 510(k). There is no basis under the proposed rules for classifying devices used in the central circulatory system in accordance with degree of risk. If it is used in the central circulatory system, a device is automatically deemed Class D.

Ms. Ginette Michaud
May 18, 2004
Page Three

Similarly, the rules would also classify as Class D products that come in contact with the nervous system, including neurological catheters. Many such products are currently classified by the FDA as Class II. Again, as stated in the "General Principles" section of the GHTF document, device classification should be predicated on degree of risk, and not merely on anatomical area of use.

Rule 13 would classify all devices treated with medicinal products as Class D. The rule specifically cites heparin coated catheters and most surely would apply to catheters coated with antibiotics. These products have been considered Class II products in the United States, with the coating considered a feature of the primary device, and not changing the intended use. A similar risk based classification scheme should be adopted by GHTF.

Cook is further concerned that products it has developed to provide a structure or scaffold to facilitate host cell proliferation during the healing process will be placed in Class D although they have been classified as Class II products by the FDA. These products are made from inert acellular porcine materials. They are used to manage wounds, to reinforce and support soft tissue, to replace dura mater, for reinforcing staple lines, and for body wall reconstruction during hernia repair. These products are absorbed into the body, and replaced by host tissue. Rules 7, 8, and 14, appear to require a classification level of Class D for these devices, despite lower classification levels in the United States.

With respect to Rule 14 in particular, Cook is concerned about the automatic classification of all products containing animal tissue into Class D. Just as there are varying degrees of risk posed by varying types of medical devices, there are varying degrees of risk posed by products containing animal tissue. Assignment of these products to Class D should not be automatic, but rather should be determined by such mitigating risk factors as composition of the material, species type, potential for disease transmission, and claims desired.

Further, the determination that all accessories should be deemed to have the same classification as the principal device appears unworkable. Many devices are supplied as kits which provide as accessories very simple products, such as scissors, swabs, etc. Certainly these products should not be subject to the same regulatory requirements as a vascular stent, for example.

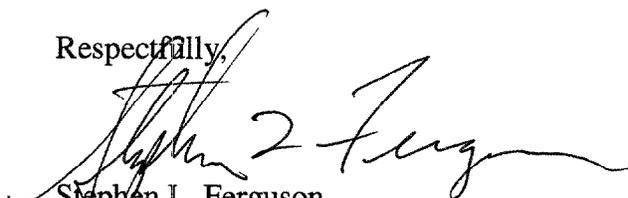
Ms. Ginette Michaud
May 18, 2004
Page Four

Finally, there are still other product areas, which raise concern for Cook, but it is particularly difficult to comment on them with certainty until the "Principles of Conformity Assessment for Medical Devices" is published. For example, biliary, ureteral, and urethral stents are classified as Class II and Class III in the United States, but the majority are cleared through the 510(k) process. These appear to be classified as Class B or C by the GHTF document, which may or may not be appropriate according to what is required by conformity assessment. That is why it is so important for GHTF to provide another opportunity to comment on classification issues after it makes public its recommendations for conformity assessment.

In the attachment, we have delineated a list of devices which we believe will be over classified under the proposed rules set out in the GHTF document. We respectfully request that GHTF modify the document to assure that such over classification does not occur. We believe that the goal of GHTF should be to devise a system that incorporates the essential determinations made in the regulatory systems of the GHTF founders, not to establish a new regulatory system, which will increase regulatory burdens and costs for governments and for industry and, in the end, impede the access of patients to important medical products.

Thank you very much for your consideration of our views.

Respectfully,

A handwritten signature in black ink, appearing to read "Stephen L. Ferguson". The signature is fluid and cursive, with a large initial "S" and "F".

Stephen L. Ferguson
Chairman of the Board

ATTACHMENT

**DEVICES AFFECTED BY PROPOSED
GHTF CLASSIFICATIONS**

Device	USA	Proposed GHTF
Vascular Wire Guides	II	D
Diagnostic Heart Catheters	II	D
Diagnostic Cerebral Catheters	II	D
Non-vascular Catheters	II	A,B,C,D ^{††††}
Gastroenterology Catheters	II	A,B,C,D ^{††††}
Selective Infusion Delivery Devices	II	B,C,D ^{††††}
Parenteral Nutrition Central Venous Catheters	II	B,C,D ^{††††}
Percutaneous Cholangiography Catheters	I	B
Visceral Infusion Catheters	II	B,C ^{†††}
Pressure Monitoring Arterial Catheters	II & III	B,C,D ^{††}
Respiratory Management Catheters	II	A,B,C ^{††}
Introduction/Drainage Catheters & Accessories	I	B,C ^{††}
Dilators	I & II	A,B,C,D ^{††}
Angioplasty Balloon Catheters	III	D
Entry/Access Needles	I	A,B,D [†]
Biopsy/Access Needles	I	A,B [†]
Breast Lesion Localization Needles	I	B
Transseptal Needles	I	A,B,D [†]
Spinal Needles	I	D
Intraosseous Access Needles	I	B
Embolization Devices	II*	C,D [†]
Introducer Catheters and Guiding Devices	II	A,B,D [†]
Percutaneous Surgical Devices	I	B,D [†]
Vessel Measure Devices	II	B,D [†]
Intravascular Retrieval Devices	II	B,D [†]
Introducer Sets	II	A,B,D ^{††††}
Gastroenterological/Urological stents	II & III	B,C ^{†††††}
Porcine-derived Wound Matrix	II	C
Porcine-derived Surgical Mesh	II	D
Porcine-derived Vascular Patch	II	D
Porcine-derived Periodontal Membrane	II	D
Porcine-derived Dural Substitute	II	D
Porcine-derived Nerve Cuff	II	D

† Depending on anatomic area

†† Depending on duration of use and anatomical area

††† Depending on duration of use and agent administered

†††† Depending on anatomical area and duration of use and agent administered

††††† Depending on duration of use

* Currently in process of being down-classified from Class III to Class II