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

RE: Medical Devices; Global Harmonization Task Force; Study Group 1: Working Draft "Medical Devices Classification" [Docket 01N-0191]

Dear Sir or Madam:

Abbott Laboratories (Abbott) submits the following comments in response to the Agency's request for comments on the Medical Devices; Global Harmonization Task Force; Study Group 1: Working Draft "Medical Devices Classification," published in the Federal Register on May 16, 2001 at 66 FR 27150.

General Comments

Unlike FDA's risk/knowledge based classification system, the Global Harmonization Task Force (GHTF) medical devices classification system is a risk-based system. Because the GHTF classification system is based solely on risk, we believe the impact of shifting from FDA's risk/knowledge based classification system will be significant. A substantial body of device knowledge and post-market experience exists. The failure to recognize such experience in determining device classification essentially eliminates decades of medical device use and benefit. Such an approach can prove detrimental to timely patient access to medical technology by creating a backlog in the regulatory product marketing system, as proven devices will be assessed as if new. In considering a new approach to medical devices classification, we believe it is important to use existing medical device knowledge and post-market experience as part of the classification procedure and as a mechanism to grandfather existing medical device classes.

Although the GHTF document recognizes subsequent reclassification of devices based on post-market experience or technological improvements (section 6.3), the document does not address classification of existing devices based on post-market experience or technological improvements. Therefore, we recommend adding a process to the document, which allows for immediate down-classification of existing devices based on knowledge and post-market experience when, under the GHTF classification procedure, such devices are elevated to a

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higher regulatory class. For example, FDA recently down-classified embolic filters (21 CFR § 870.4260) into Class II. However, it appears to us that the GHTF classification system places such filters in Class D, the highest regulatory class. An immediate down-classification procedure should be used to address such discrepancies by grandfathering the embolic filters into a lower regulatory class based on existing device knowledge and experience.

Furthermore, in discussing subsequent device reclassification the GHTF states, "[r]egulatory authorities are encouraged to include a process for changing the assigned classification of a device, when necessary and to consult with their international counterparts when considering reclassification of a device." Without a defined process, it is difficult to imagine how such reclassification on an international level will occur. The potential for disjointed device reclassification is significant, defeating the goal of harmonization. We suggest the GHTF develop a defined process for subsequent reclassification as part of the Medical Devices Classification document or as a companion document.

Similarly, a universal classification system for medical devices would be useful only if most major countries agree to participate and use the system without significant modifications. Modification of the classification system by a country to individualize the system will diminish the system's usefulness. Variance in rule interpretation among countries will also limit the intent and usefulness of adopting a universal classification system. To ensure consistent application of device classifications across countries we suggest the development of a central repository to maintain assigned device classifications.

One beneficial aspect of using medical device features as part of the classification system would be the additional level of objectivity and predictability in the classification process. This particular component of the proposed GHTF system, along with a knowledge-based system, would incorporate key aspects of medical device use and the development process.

In summary, adaptation of this classification system will involve time and resources on the part of both FDA and industry. If the Agency adopts these recommendations to its own regulatory requirements, then some type of grandfather provision for existing device classes would be needed, as well as incorporation of device knowledge and post-market experience into the classification system.

Specific Comments

1. Section 2.0 Scope

We suggest incorporating the definition of "medical device" under sections 2.0, Scope or 4.0, Definitions. In vitro diagnostic (IVDs) were specifically excluded from the scope of the document. We recommend the GHTF describe its intent regarding the classification of IVDs.

2. Section 4.0 Definitions

We recommend including a definition of the term "biological effect," which is used in rules 6 and 7.

3. Section 6.0 Recommendations

6.1 Primary Recommendations
We recommend that determination of class consider the intended use of the device.

6.2 Factors Influencing Device Classifications
This section indicates that regulatory authorities may assign names/numbers of the individual risk classes based on local preference. It is recommended to identify the four classes in a common manner that is recognized by all countries instead of allowing local preference to identify the classes. With the goal of harmonization, the identification of classes should be harmonized along with the classification process.

6.4 Proposed General Classification System for Medical Devices – Figure 1
We recommend revising figure 1, General Classification System, by providing a more detailed definition of each risk level based on the information contained in the classification rules and flow diagram. Device examples are provided, but information on device characteristics for each risk level is not provided. We recommend adding a column for device characteristics. Once the characteristics have been defined, it would be appropriate to reassess the levels of risk identified in the document.

4. Section 8.0 Classification Rules

Rule 1
The description of non-invasive, unlike FDA's definition, of non-invasive does not include simple venipuncture used for blood sampling (see 21 CFR 812.3(k)). Based on device history and experience, inclusion of simple venipuncture as non-invasive is appropriate, and we recommend the GHTF adopt this item.

Rule 6
We recommend clarifying the last bullet point of rule number 6 which states "intended for transient use are in Class B unless they are intended to administer medicines by means of delivery system, if this is done in a manner that is potentially hazardous taking account of the mode of application, in which they are in Class C." It is unclear how one would make this determination. Clarification is recommended, in addition to the definition of "potentially hazardous manner," which has already been provided.

Thank you for the opportunity to provide these comments and for your consideration of our comments. Should you have any questions, please contact April Veoukas at (847) 937-8197 or by facsimile at (847) 938-3106.

Sincerely,

fw:

Douglas L. Sporn
Divisional Vice President
Corporate Regulatory Affairs, Abbott Laboratories

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