Kensey Nash

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

9676 '01 JUL -2 P1:16

RE: Medical Devices; Global Harmonization Task Force; Study Group 1; Working Draft "Medical Devices Classification"

Dear Sir or Madam:

I am writing to comment on the above-referenced draft document from the GHTF. Generally, I am in agreement with the proposed classification scheme. I believe that a risk-based approach such as proposed in this document is an appropriate method of classifying medical devices. This type of approach, now in use in the EU through the CE-marking process, seems to be a much more logical system than the current 510(k)/PMA system in the U.S. We would encourage the FDA to consider adopting such a system for regulating devices in the U.S.

I have the following specific comments on the draft document:

1. Devices that are "mainly absorbed" appear under three different rules, surgically invasive-transient, surgically invasive-short term, and surgically invasive-long term/implantable. Because they appear in a number of categories, with different resulting classifications, it is not at all clear to me where certain devices would be classified. For example, an absorbable orthopedic fixation screw would be of surgically transient use but is an implant and absorbs over about 12 months. Either further descriptions should be added to clarify the distinctions between absorbable implants and non-absorbable implants under the various rules or the scheme should be simplified to have all absorbable implants in one classification rule.
2. I do not agree that long-term absorbable implants should be classified into Class D, as in Rules 7 and 8. Many such implants are very innocuous and are made from materials that have a long history of safe medical use. An absorbable orthopedic screw does not seem to warrant the same level of regulatory oversight as a pacemaker or brachytherapy device.

Thank you for the opportunity to comment on this document.

Sincerely,

Julie N. Broderick
Vice-President of Clinical and Regulatory Affairs

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