



Medical Products Group

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

RE: Reclassification of the Intervertebral Body Fusion Device; Proposed Rule
[Docket 2006N-0019]

RE: Intervertebral Body Fusion Device; Availability of Draft Guidance
[Docket 2006D-0020]

Dear Sir or Madam:

Abbott Laboratories submits these comments regarding the following items published in the Federal Register on February 9, 2006, FDA's proposed rule to reclassify intervertebral body fusion devices published at 71 FR 6710 and FDA draft guidance "Class II Special Controls Guidance Document: Intervertebral Body Fusion Device" published at 71 FR 6778.

Thank you for the opportunity to provide these comments on both the proposed rule and the draft guidance. Abbott endorses the reclassification of intervertebral body fusion devices from Class III to Class II.

We note that the use of intervertebral body fusion devices at different spinal levels (e.g., thoracic) was discussed at the Orthopedic and Rehabilitation Devices Panel meeting on December 11, 2003. Although the reclassification under discussion was for existing products, the agency indicated it would evaluate different spinal levels under the 510(k) process to determine whether or not the sponsor had demonstrated substantial equivalence to already cleared products.¹

As the agency has done for vertebral body replacement devices (FDA product code MQP), we recommend incorporating the thoracic spine into the lumbar spine and adding thoraco-lumbar to the proposed classification regulation. By grouping the thoracic spine along with the lumbar spine for the vertebral body replacement devices, the agency has established a precedent. We feel it is appropriate to follow this same model for

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interbody fusion devices. The anatomical loads for the thoracic region are less than that for the lumbar region; therefore if a device performs in an acceptable manner when tested in a lumbar model (i.e., per ASTM standards), the worst-case test set-up (lumbar vs. thoracic) has been evaluated.

Alternatively, we recommend the agency address this item in the proposed guidance document under Scope (section 4) by adding, "The Orthopedics Devices Branch is available to advise you regarding demonstrating substantial equivalence of intervertebral body fusion devices at different levels (e.g. thoracic)."

In regards to Material Characterization (section 7 of the proposed guidance), for materials that have extensive use in existing intervertebral body fusion devices or vertebral body replacement devices, such as titanium alloys and PEEK, we recommend that the agency, in accordance with its least burdensome principles, clarify that limited biocompatibility data would be expected in the 510(k) submission, such as data summaries or references to use of identical materials in similar use. Specifically, we anticipate that a material cleared for use in a vertebral body replacement device would not present new biocompatibility concerns and recommend the agency address this item in the guidance document.

Should you have any questions, please contact me at (847) 937-8197 or by facsimile at (847) 935-0766.

Sincerely,

April Veoukas, J.D.
Director, Regulatory Affairs
Medical Products Group
Abbott Laboratories

¹ Reference is made to the following statement by Dr. Witten, "[a]s far as some of the other things, the use with allograft bone, and the spinal levels, and the other materials, I will just make the following generic comments, which is that we can only reclassify what we've actually seen. That is what we have actually approved. So the reclassification would be for, you know, the existing products. And then what would happen, if a sponsor came in with something different, a different material, or a different level, or to be used with a different something other than allograft, is we would evaluate that through the substantial equivalence process, and see whether or not the product with data, or without, with whatever the sponsor provided, was able to demonstrate substantial equivalence to the products that we had already cleared. And so based on that substantial, the review process, we might decide that we need some types of additional information, or not, and could include, you know, anything could include bench testing, animal testing, potentially clinical data. So that would be part of the review process. So, in other words, in our minds this would leave it open to have these different types of devices, but we would need a demonstration of substantial equivalence in order to make that determination. "