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From the office of:
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May 5, 2006

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

RE: Docket No. 206N-0019, Reclassification of the Intervertebral Body Fusion Device.

Dear Sir or Madam:

DePuy Spine, Inc., a manufacturer of devices to treat spinal disorders, including a Lumbar Interbody Fusion Cage System, approved by FDA in 1999 (P960025), would like to express its full support for the reclassification of the Intervertebral Body Fusion Device as stated in the Proposed Rule and published in the Federal Register / Vol. 71, No 27 / Thursday, February 9, 2006. No changes are requested to either the Rule or the *Class II Special Controls Guidance Document: Intervertebral Body Fusion Device*.

The Orthopaedic and Rehabilitation Devices Panel met on Thursday, December 11, 2003 to make a recommendation to the Food and Drug Administration on the FDA-proposed reclassification of the intervertebral body fusion device. The Panel voted unanimously to recommend that FDA reclassify the device into Class II. Despite the unanimous support of the Panel, and support from FDA and private industry, it has taken more than two years to publish the proposed rule. DePuy Spine would welcome every effort to expedite the final publication of this reclassification rule.

The reclassification language is not specific regarding design, materials or treatment levels of the spine. DePuy Spine encourages FDA to consider the Least Burdensome Provisions of the FDA Modernization Act of 1997 and limit the burden of clinical data requested to establish equivalence under this rule.

DePuy Spine appreciates FDA's efforts in support of this reclassification effort and looks forward to the expeditious publication of the final rule.

Sincerely,



William Christianson
Worldwide Vice President of Regulatory Affairs

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