

ALPHATEC OF SPINE INC.

May 10, 2006

Division of Dockets Management 6 MAY 11 A 7:01
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 FDA:

Alphatec Spine, Inc. 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 the Rule. We have one comment regarding the *Class II Special Controls Guidance Document: Intervertebral Body Fusion Device*.

Section 11 of the guidance regarding Sterility states:

"The device should be sterile with a sterility assurance level (SAL) of 1×10^{-6} using a sterilization cycle that has been validated in accordance with the quality system regulation (21 CFR Part 820)."

It is not uncommon for manufacturers to provide this type of product non-sterile to be sterilized with the instrument kit by the hospital before use. Sterilization parameters are validated by the manufacturer and provided in the package insert instructions. The requirement as stated should not require product to be sold sterile.

Alphatec Spine encourages FDA to finalize this reclassification as quickly as possible and in implementation 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.

Regards,


Robert Zoletti
VP Clinical and Regulatory Affairs

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