DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR - 5 2006

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Thomas G. Williams
Director, Business Assurance/Official Correspondent
CooperSurgical, Inc.
95 Corporate Drive
Trumbull, CT 06611

Re: Change in Classification Petition **2005P-0431**

Dear Mr. Williams:

This letter responds to your petition, dated August 18, 2005, regarding the McCue CUBA Clinical™ Ultrasonic Bone Sonometry System. Based on new information on the benefits and risks of bone sonometers since these devices were classified into class III, the Food and Drug Administration (FDA or the agency) has initiated their reclassification from class III to class II when intended for determining the possible presence of osteoporosis and assessing fracture risk; monitoring bone changes over time; and/or assessing non-age-related bone loss. In the February 15, 2006, issue of the Federal Register, FDA published a proposed rule and a notice announcing the availability of a draft guidance that would support this reclassification. For your reference, copies of these documents are enclosed.

The agency believes that this rulemaking addresses the request made in your petition, and therefore, we are closing the petition. If you have further questions regarding reclassification, please contact Ms. Marjorie Shulman at 301-594-1190, extension 144. For scientific questions regarding your submission, please contact Dr. Robert A. Phillips by e-mail (RobertA.Phillips@fda.hhs.gov) or by telephone at 301-594-1212, extension 131.

Sincerely yours,

Linda S. Kahan

Linda S. Kahan
Deputy Director
Center for Devices and
Radiological Health

Enclosures (3)

cc: Donna Bea Tillman, M.D., HFZ-400
Director, Office of Device Evaulation

2005P-0431

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