DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 1 2003 03 OCT 29 P4:40

Mr. William Christianson
President
Orthopedic Surgical Manufacturers Association
1962 Deep Valley Cove
Germantown, TN 38138

Re: Docket No. 02P-0294; Request for Clarification
Reclassification of Polymethylmethacrylate (PMMA) Bone Cement, (21 CFR 888.3027)/Docket No.98P-0035

Dear Mr. Christianson:

I am writing to you as a follow-up to our response to the May 6, 2003, clarification request made by Howmedica Osteonics Corporation regarding the reclassification of PMMA bone cement. Pursuant to Section 520(1)(2) of the Federal Food, Drug, and Cosmetic Act (the Act) the Food and Drug Administration (FDA) issued an order reclassifying PMMA bone cement from class III (premarket approval) into class II (special controls). FDA believes that a general indication of pathological fractures, based upon data from pathological fractures due to tumor in long bone, was not excluded from the reclassification action. Therefore, PMMA bone cement labeled for the general indication of pathological fractures is within the scope of the reclassification action and is regulated under 21 CFR 888.3027 as a class II device.

Prior to the reclassification action, one holder of an approved premarket approval application had the following indication for use:

> "The cement is also indicated for the fixation of pathological fractures where loss of bone substance or recalcitrance of the fracture renders more conventional procedures ineffective."

Please note that in order to change the indication for use for a legally marketed PMMA bone cement to include this indication for use requires the submission of a new 510(k). It should also be noted that clinical data may be needed to support 510(k) marketing authorization, depending on the specific indications for use (e.g., pathological or compression fractures due to osteoporosis) that you may seek. In this regard, we encourage the conduct of well designed clinical trials aimed at addressing the safety and effectiveness questions that specific indications for use may present.

We believe this clarification letter closes Docket No. 02P-0294. The information contained in Docket No. 02P-0294, along with a copy of this letter, will be added to Docket No. 98P-0035 as an amendment.

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If you have any questions concerning the content of this letter, please contact Mr. Hany Demian, at (301)594-2036, extension 184.

Sincerely yours,

Philip J. Phillips
Deputy Director for Science
and Regulatory Policy
Office of Device Evaluation
Center for Devices and
Radiological Health