



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Jerome J. Klawitter, Ph.D.  
President and CEO  
Ascension Orthopedics, Inc.  
8200 Cameron Road, Suite C-140  
Austin, Texas 78754

NOV 19 2001

Re: P000057  
Ascension MCP  
Filed: February 20, 2001  
Amended: February 20, March 16, June 8, June 29, July 6, July 11, October 26,  
October 31, and November 15, 2001  
Procode: NEG

Dear Dr. Klawitter:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your premarket approval application (PMA) for the Ascension MCP. This device is indicated for use as a total joint replacement of index, long, ring, and small finger metacarpophalangeal (MCP) joints that exhibit symptoms of pain, limited motion, or inadequate bony alignment (i.e., subluxation/dislocation) secondary to articular destruction or degenerative disease related to rheumatoid arthritis, systemic lupus erythematosus, osteoarthritis, or post-traumatic arthritis where soft tissue reconstruction can provide adequate stabilization. We are pleased to inform you that the PMA is approved subject to the conditions described below and in the "Conditions of Approval" (enclosed). You may begin commercial distribution of the device upon receipt of this letter.

The sale, distribution, and use of this device are restricted to prescription use in accordance with 21 CFR 801.109 within the meaning of section 520(e) of the Federal Food, Drug, and Cosmetic Act (the act) under the authority of section 515(d)(1)(B)(ii) of the act. FDA has also determined that, to ensure the safe and effective use of the device, the device is further restricted within the meaning of section 520(e) under the authority of section 515(d)(1)(B)(ii) insofar as the sale, distribution, and use must not violate sections 502(q) and (r) of the act.

In addition to the postapproval requirements in the enclosure, you have agreed to provide the following information:

1. In order to evaluate the effect of your revised rehabilitation therapy protocol in the early post-operative period, you will conduct a post-approval study to obtain 12 months of post-operative data on each Ascension MCP device implanted in a minimum of 100 patients at 4 sites, including Mayo Clinic, Rochester Minnesota, USA. This information

will be collected on patients for whom this device is indicated. You will submit the protocol for your post-approval study within 30 days of receipt of this letter.

- a. Your post-approval study protocol will address:
    - (i) The method(s) used to select the patients and sites; and
    - (ii) A description of how you intend to minimize the number and analyze data of patients lost-to-follow-up.
  - b. The data from the post-approval study will be submitted to the FDA as part of your annual report and will include the following data collected for rheumatoid arthritis, systemic lupus erythematosus, osteoarthritis and post-traumatic arthritis patients at surgery/immediate post-op, 6 weeks, 12 weeks, 6 months and 12 months:
    - (i) Complications and adverse events including clinically and radiographically determined recurrent metacarpophalangeal joint deformity, subluxation, and dislocation; soft tissue joint reconstruction; synovitis, and infection; and
    - (ii) Clinically determined joint function including range of motion, extension deficit, and active flexion; and
2. If there are any implant revisions necessary during the 12 months of follow-up on any of the patients identified in item 1 above, a second objective will be to evaluate your modified device removal procedures and instrumentation. Therefore, you will perform, where possible, a retrieval analysis of all Ascension MCP devices that are implanted and subsequently removed during implantation or revision procedures including a description of all device fractures, generation of wear or particulate debris, and the adequacy of removal instrumentation and procedures.

Please be advised that the results of the post-approval study outlined in items 1 and 2 above must be reflected in the labeling (via a supplement) when the post-approval study is completed.

CDRH will notify the public of its decision to approve your PMA by making available a summary of the safety and effectiveness data upon which the approval is based. The information can be found on the FDA CDRH Internet HomePage located at <http://www.fda.gov/cdrh/pmapage.html>. Written requests for this information can also be made to the Dockets Management Branch, (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. The written request should include the PMA number or docket number. Within 30 days from the date that this information is placed on the Internet, any interested person may seek review of this decision by requesting an opportunity for administrative review, either through a hearing or review by an independent advisory committee, under section 515(g) of the Federal Food, Drug, and Cosmetic Act (the act).

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Failure to comply with the conditions of approval invalidates this approval order. Commercial distribution of a device that is not in compliance with these conditions is a violation of the act.

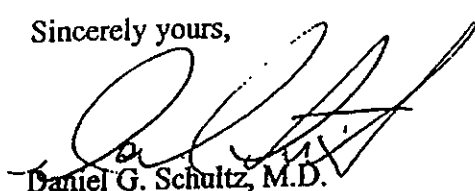
You are reminded that, as soon as possible and before commercial distribution of your device, you must submit an amendment to this PMA submission with copies of all approved labeling in final printed form. The labeling will not routinely be reviewed by FDA staff when PMA applicants include with their submission of the final printed labeling a cover letter stating that the final printed labeling is identical to the labeling approved in draft form. If the final printed labeling is not identical, any changes from the final draft labeling should be highlighted and explained in the amendment.

All required documents should be submitted in triplicate, unless otherwise specified, to the address below and should reference the above PMA number to facilitate processing.

PMA Document Mail Center (HFZ-401)  
Center for Devices and Radiological Health  
Food and Drug Administration  
9200 Corporate Blvd.  
Rockville, Maryland 20850

If you have any questions concerning this approval order, please contact Mr. John S. Goode at (301) 594-2036, ext. 155.

Sincerely yours,



Daniel G. Schultz, M.D.  
Deputy Director for Clinical  
and Review Policy  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure