August 10, 1999

Mr. James Morgan
Director of Quality Assurance and Regulatory Affairs
TMJ Implants, Incorporated
17301 West Colfax Avenue, Suite 135
Golden, Colorado 80401

Re: P990003
TMJ Fossa Eminence/TMJ Condylar Prosthesis System
Filed: February 12, 1999
Amended: March 22, March 30, April 12, April 13, April 27, and July 26, 1999

Dear Mr. Morgan:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has reviewed the above premarket approval application (PMA) and your request dated July 23, 1999 for continued availability of the device for public health need. CDRH also has taken into consideration the recommendations of the May 11, 1999 Dental Products Panel meeting in reaching the following decision.

As stated in the final rule published in the Federal Register of December 30, 1998, a PMA was required to be submitted for all total temporomandibular joint prostheses by March 30, 1999. Under Section 515(d)(1)(B)(i) of the Federal Food, Drug, and Cosmetic Act, FDA may not agree to extend the review period for a PMA for a preamendments device unless the agency finds that the continued availability of the device is necessary for the public health.

This is to notify you that CDRH has determined that continued availability of the Fossa Eminence Prosthesis, not including the Patient-Specific Fossa Eminence Prosthesis, is necessary for the public health. The Fossa Eminence Prosthesis is the only device currently available for patients with meniscal perforation who need this partial implant. This patient population does not have alternative treatments available. Therefore, while CDRH completes the processing of your PMA, including resolution of remaining outstanding issues, the Fossa Eminence Prosthesis may remain in commercial distribution for the indication identified above.

If you have any questions concerning this matter, please contact Ms. Angela Blackwell, at (301) 827-5283.

Sincerely,

/s/

Susan Alpert, Ph.D., M.D.
Director
Office of Device Evaluation
Center for Devices and
Radiological Health