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Re: ATS Open Pivot Bileaf Heart Valve  
Docket No. 02E-0344

The Honorable Jon Dudas  
Under Secretary of Commerce for Intellectual Property and  
Director of the United States Patent and Trademark Office  
Box Pat. Ext.  
P.O. Box 1450  
Alexandria, VA 22313-1450

JUL - 8 2005

Dear Director Dudas:

This is in regard to the application for patent term extension for U.S. Patent No. 5,354,330, filed by ATS Medical, Inc., under 35 U.S.C. § 156 et seq. We have reviewed the dates contained in the application and have determined the regulatory review period for ATS Open Pivot Bileaf Heart Valve, the medical device claimed by the patent.

The total length of the regulatory review period for ATS Open Pivot Bileaf Heart Valve is 1,418 days. Of this time, 980 days occurred during the testing phase and 438 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date an exemption under section 520(g) of the Federal Food, Drug, and Cosmetic Act involving this device became effective: November 27, 1996.

FDA has verified the applicant's claim that the date the investigational device exemption (IDE) required under section 520(g) of the Federal Food, Drug, and Cosmetic Act for human tests to begin became effective on November 27, 1996.

2. The date the application was initially submitted with respect to the device under section 515 of the Federal Food, Drug, and Cosmetic Act: August 3, 1999.

FDA has verified the applicant's claim that the premarket approval application (PMA) for ATS Open Pivot Bileaf Heart Valve (PMA P990046) was initially submitted on August 3, 1999.

3. The date the application was approved: October 13, 2000.

FDA has verified the applicant's claim that PMA P990046 was approved on October 13, 2000.

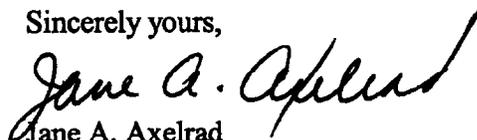
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This determination of the regulatory review period by FDA does not take into account the effective date of the patent, nor does it exclude one-half of the testing phase as required by 35 U.S.C. § 156(c)(2).

Please let me know if we can be of further assistance.

Sincerely yours,



Jane A. Axelrad  
Associate Director for Policy  
Center for Drug Evaluation and Research

cc: Orrin M. Haugen  
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