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October 22, 2004

Office of Device Evaluation  
CDRH  
9200 Corporate Blvd.  
Rockville, MD 20850

**Re: Docket Number 2004P-0457/CCP 1: Reclassification of Non-constrained, Mobile-Bearing Ankle Prosthesis**

Dear Mr Phillipps:

In response to the FDA letter dated September 27, 2004, and to our telephone conference on September 13, 2004 please find attached an updated version of the reclassification of non-constrained, mobile-bearing ankle prostheses. We have integrated more recent references to bring the Agency up to date with current publications and have added sections including Engineering drawings/Specifications and Special Controls.

Your questions cited in the above-mentioned letter were reviewed and we have formulated the following response:

1. An explanation of the unique patient populations and a separation of IDE data is provided (See section 4. The predecessor: B-P Total Ankle System (Shallow Sulcus) and section 5. B-P Total Ankle System (Deep Sulcus).
2. All Preclinical Testing and in vivo testing is applicable and was performed on the Buechel-Pappas Ankle design (Deep Sulcus).
3. An explanation of specific designs with the clinical data is presented (See section 4. The predecessor: B-P Total Ankle System (Shallow Sulcus) and section 5. B-P Total Ankle System (Deep Sulcus).
4. With regard to special controls we have provided a Special Controls guidance document (See Appendix D: Special Controls) and have updated the petition to reflect how the Endotec device mitigates these risks of device failure and establish why premarket approval is not necessary to provide reasonable assurance of safety and effectiveness.

2003P-0477

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October 21, 2004

In light of the recent collaborative spirit demonstrated by the Agency and the receipt of the filing of the Buechel-Pappas Unconstrained Ankle Prosthesis reclassification petition (assigned docket number 2004P-0457/CCP 1), we wish to withdraw the pending Citizen Petition to conserve Agency resources and focus on our request for reclassification.

If you have any questions, please do not hesitate to call.

Sincerely



Michael J. Pappas Ph.D., P.E.  
President, Endotec

Encl.