



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 27 2004

Michael J. Pappas, Ph.D.
President
Endotec, Incorporated
20 Valley Street
South Orange, New Jersey 07079

Re: Reclassification of Non-Constrained, Mobile-Bearing Ankle Prosthesis
Dated: September 4, 2001
Received: September 6, 2001

Dear Dr. Pappas:

This letter is a follow-up to our September 13, 2004, telephone conference regarding the reclassification petition for non-constrained, mobile-bearing ankle prosthesis, submitted in accordance with Section 513(e) of the Federal Food, Drug, and Cosmetic Act, on September 6, 2001. Additionally, it addresses the Citizen Petition filed by the agency on October 8, 2003.

Before getting into the substance of your reclassification petition, I want to acknowledge the collaborative spirit of our telephone conference. From a Food and Drug Administration (FDA) perspective, we engaged in a very productive dialogue that established clear objectives and reasonable expectations. As we move forward, we will maintain our commitment to affording your company a fair and impartial opportunity to present your arguments in support of reclassifying non-constrained, mobile-bearing ankle prostheses into class II, subject to special controls.

As indicated during our telephone conference, we are forwarding your reclassification petition to FDA's Division of Dockets Management with a recommendation that the petition be filed. You should receive a letter from them shortly that will identify the official filing date with a docket number for your reclassification petition. At that time, your reclassification petition will be placed on public display and you will be instructed to submit any future correspondence regarding the petition to the Division of Dockets Management with a clear reference to your docket number.

As you know, we recently began a substantive review of your petition and have identified 3 significant areas of deficiency that preclude further review at this time. In order for us to complete our evaluation, we need for you to address the following issues:

1. Your request for reclassification relies on clinical data, including data collected under your approved investigational device exemptions (IDE) application and data from the

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published literature. Before we can conduct an in-depth assessment of this information, we need to know whether each source of information involves a unique patient population, or there is patient overlap with the same patient results being reported in multiple data sources. Additionally, we would appreciate your segregating all data collected under your IDE. Where segregation is impossible, we request that you identify those literature sources that contain your IDE data.

2. Given that your device design, including materials, may have evolved over time, we request that you link your specific designs with the preclinical testing presented in your reclassification petition. If the testing involved only one design, please confirm this.
3. As indicated in the previous item, your device design, including materials, may have evolved over time. Please link your specific designs with the clinical data presented in your reclassification petition. If all clinical results involved only one design, please confirm this.
4. In order for a device to be placed in class II, special controls must be able to be established that, when combined with the general controls, will provide a reasonable assurance of safety and effectiveness for the general device classification of non-constrained, mobile-bearing ankle prosthesis. Given that you have reported clinical failures with your device when used in accordance with your IDE, and with other devices in published literature, we request that you address how your proposed special controls will mitigate the risks of device failure. For a successful reclassification into class II, you will need to establish why premarket approval is not necessary to provide reasonable assurance of safety and effectiveness. Keep in mind, the special controls will include controls that are general (e.g., biocompatibility) and controls that are specific to non-constrained, mobile-bearing ankle prostheses (e.g., constraint testing).

We appreciate your interest in ensuring that your petition includes any updated data that may have become available from any clinical experience with your device in the United States and Europe. If you have access to data from any additional experience with your device, we would appreciate your addressing the issues identified in the first three items outlined above. It is particularly important that any additional data you provide be linked to a particular device design and that we know if any reports involve overlapping clinical experience.

Once you provide the requested information, we will once again begin a substantive evaluation of your reclassification petition. Based on the current status of the petition and our need for additional information, we envision being able to take your reclassification petition before the Orthopedics Devices Panel for a review and recommendation in early 2005. We have not yet established dates for the meetings of this Panel, but we will make every effort to convene a meeting at a date that will result in a timely review of your reclassification request. Once we receive your response to this letter and have an opportunity to review it, we will contact you to discuss possible panel meeting dates.

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Given your agreement that the actions we are taking in regard to your reclassification petition address the concerns expressed in your pending Citizen Petition, we appreciate your willingness to withdraw it upon your receipt of a filing letter from our Division of Dockets Management. Your withdrawal of the Citizen Petition will conserve Agency resources and will permit us to focus on your request for reclassification.

In closing, I want to remind you that the burden for establishing an adequate basis to support your proposed reclassification rests with you as the petitioner. We will work with you to facilitate an understanding of our procedures and statutory requirements. If you have any questions related to reclassification, please contact Ms. Marjorie Shulman at (301) 594-1190, ext. 144. For scientific and technical assistance, please contact Ms. Hollace Saas Rhodes at (301) 594-2036, extension 165 or by email (hollace.rhodes@fda.hhs.gov).

Sincerely yours,

A handwritten signature in black ink, appearing to read "Philip J. Phillips". The signature is written in a cursive style with a large, prominent "P" at the beginning.

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