ENDOTEC

ATTACHMENT E

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 25 2002

Mr. Joseph Ayers
P. O. Box 25
Yellow Springs, Ohio 45387

Dear Mr. Ayers:

I am writing in response to your letter to Dr. Bernard Schwetz, Acting Principle Deputy Commissioner, Food and Drug Administration. In your correspondence, you expressed your desire to gain access to the Buechel-Pappas Ankle Replacement Device under the Food and Drug Administration (FDA) compassionate use provision.

Under the Federal Food, Drug, and Cosmetic Act, patients are permitted access to investigational devices without being part of a clinical study under certain circumstances. (Such access is referred to as "compassionate use.") Compassionate use requests are reviewed on a case-by-case basis and are evaluated by weighing the anticipated benefits of the investigational device against the potential risks to the subjects, taking into account each patient's medical condition and the alternative medical options available to the patient. This assessment is performed using the medical information on the specific patient as presented from the referring physician as well as the data presented to FDA by the study sponsor in their study progress reports.

In the case of the Buechel-Pappas Ankle Replacement Device, a recent FDA inspection of the device manufacturer, Endotec, Incorporated found the data from the study of the Buechel-Pappas Ankle to be unreliable. Due to these inspectional findings, and the potential for unknown safety concerns, we have not been able to approve the recent compassionate use requests presented to us for evaluation. FDA believes that, until the data are provided to determine if the anticipated benefits of the Buechel-Pappas Ankle outweigh the potential risks, patients who require a total ankle replacement should consider one of the other medical options identified below.

Currently, the following options exist for the treatment of severely arthritic ankles:

1. ankle fusion;

2. legally marketed, constrained, ankle replacement device (e.g., DePuy Agility Ankle); and

3. other investigational ankle replacement devices. Although we cannot disclose information regarding investigational devices, there is one investigational device that has been publicly acknowledged in the medical literature, specifically, the

Scandinavian Total Ankle Replacement (S.T.A.R.)[1,2,3] being investigated by Link Orthopaedics, Inc.

Unfortunately, our regulations do not allow us to share any information regarding an investigational device with anyone other than the person sponsoring the clinical trial or their authorized agents. Therefore, we are prohibited from discussing the S.T.A.R. study or the Buechel-Pappas study with you. We recommend you or your physician communicate directly with the study sponsors about your questions.

We regret that we cannot provide you with any additional information, but we hope you and your physician find this information helpful.

Sincerely yours,

for Mark N Melkerson

Celia Witten, Ph.D., M.D.
Director
Division of General Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

[1] American Academy of Orthopaedic Surgeons 2001 Annual Meeting; State of the Art in Total Ankle Arthroplasty: "Scandinavian Total Ankle Rationale & Design", M.J. Coughlin.
[2] Mayo Clinic Jacksonville News, "Daytona Beach woman has six artificial joints including new ankle implants"; Erik Kaldor, January 24, 2001.
[3] University of Pennsylvania Orthopaedic Journal, "Evolution of Total Ankle Arthroplasty", S. Sodha, S.Y. Wei, E. Okereke, Vol. 13, Spring 2000, pp. 18-21.