

**UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
ORLANDO DIVISION**

UNITED STATES OF AMERICA,

Plaintiff,

-vs-

Case No. 6:06-cv-1281-Orl-18KRS

**ENDOTEC, INC.,
MICHAEL J. PAPPAS,
FREDERICK F. BUECHEL,**

Defendants,

JUDGMENT IN A CIVIL CASE

DECISION BY COURT: This action came to trial before the Court. The issues have been tried and a decision has been rendered.

IT IS ORDERED AND ADJUDGED:

that Judgment is hereby entered in favor of Defendants Endotec, Inc., Michael J. Pappas and Frederick F. Buechel and against the Plaintiff, United States of America, in regard to the subject ankle devices. Each ankle device was a custom device and exempt from premarket approval requirements.

that Judgment is hereby entered in favor of Plaintiff, and against Defendants, in regard to the FlexGlide Knee Bearing with Anterior Stop and the Fenning Modular Bearing.

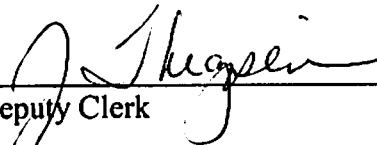
that Judgment is hereby entered in favor of Defendants, and against the Plaintiff, in regard to H-P TMJ devices and the Hemi TMJ. Distribution of the H-P TMJ devices was not a deviation from the approved investigational plan. The Hemi TMJ is a custom device.

IT IS FURTHER ORDERED that approved export devices must be properly labeled as intended for export and Defendants shall not sell or advertise in domestic commerce without FDA approval. Defendants are enjoined from advertising the B-P Ankle

or any custom ankle devices through websites, in professional journals, at professional conferences, or through any other means and the ankle devices may be used by prescription only. Defendants must strictly adhere to FDA's requirements for monitoring clinical studies. Additionally, Defendants are enjoined from manufacturing, packing, labeling, and distributing the FlexGlide Knee Bearing with Anterior Stop and the Fenning Modular Bearing, unless and until Defendants obtain an approved investigational device exemption, premarket approval, or 510(k) clearance.

Plaintiff shall take nothing and each party shall be responsible for its own attorney's fees and costs.

SHERYL L. LOESCH, CLERK

BY: 
Deputy Clerk

EOD: May 1, 2008