

DEPARTMENT OF HEALTH AND HUMAN SERVICES

MEMORANDUM

Food and Drug
Administration
Office of Device Evaluation
9200 Corporate Boulevard
Rockville, MD 20850

Date: August 10, 1998
From: Charles M. Durfor, Ph.D.
To: Panel Members
Subject: Guidance for the Preparation of a Premarket Notification Application for Processed Human Dura Mater.

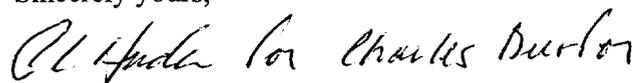
Dear Panel Member:

At the Neurological Devices Advisory Panel (the Panel) meeting scheduled for September 16 and 17, 1999, you will be involved in a general discussion regarding the guidance document entitled, "Guidance for the Preparation of a Premarket Notification Application for Processed Human Dura Mater" (attached). The purpose of this document is to provide guidance to providers of processed human dura mater devices on important preclinical, clinical, and labeling information that should be presented in premarket notification (510(k)) applications. Please review the guidance document and the accompanying questions for discussion at the panel meeting.

If you have any questions about the guidance document you may contact Charles M. Durfor, Ph.D., Reviewer, Plastic and Reconstructive Surgery Devices Branch at (301) 594-3090.

Please contact Ms. Jan Scudiero, Executive Secretary for the Neurological Devices Panel, at 301-594-1184, for questions regarding the scheduled panel meeting.

Sincerely yours,



Charles M. Durfor, Ph.D.
Reviewer
Plastic and Reconstructive Surgery Devices Branch