DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Chicago District Office
Central Region
300 S. Riverside Plaza
5th Floor, Suite 550 South
Chicago, IL 60606
Telephone: (312) 353-5863
FAX: (312) 886-3280

April 11, 2000

Dear

I have collected information from our FDA web site that, I hope, assists your communications with your insurance company.

I have also contacted our Center for Devices and confirmed that, Cranial Technologies, Inc., located in Phoneix, AZ, has obtained clearance from the FDA to market their Dynamic Orthotic Cranioplasty - DOC™ Band. On May 29, 1998, FDA gave Cranial Technologies, Inc. clearance to market this device in accordance with FDA's Premarket Notification 510(k) regulations. FDA's premarket notification identification number for the DOC™ Band is K964992. I have enclosed a page from FDA's web site (www.fda.gov) that documents FDA's marketing clearance for this device.

Additionally, I have also included documents that show Cranial Technologies has listed this device and registered their facility in accord with FDA regulations. I have enclosed reading material that explains FDA's marketing, listing, and registration requirements.

* FDA does **not** consider the Dynamic Orthotic Cranioplasty - DOC™ Band to be an investigational device, as long as it is being marketed with the same design and indications for use that were documented in its premarket notification.

If you wish to obtain a copy of any FDA inspection reports regarding your complaint (FDA Complaint No. CHI-6428), you can make a request in accord with the Freedom of Information Act (FOIA). I have enclosed instructions to make such a request.

If I can be of further assistance to you, please don't hesitate to contact me at 312-353-5863 x171.

Sincerely,

Michael A. Lang

Michael A. Lang
Compliance Officer

Enclosures