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Food and Drug Administration  
Kansas City District  
Southwest Region  
11630 West 80<sup>th</sup> Street  
P.O. Box 15905  
Lenexa, Kansas 66285-5905  
Telephone: (913) 752-2100

April 9, 2001

**CERTIFIED MAIL  
RETURN RECEIPT REQUESTED**

**WARNING LETTER  
REF KAN-2001-016**

Mr. David Osterman, President  
Orthotic and Prosthetic Lab, Inc.  
748 Marshall Avenue  
St. Louis, MO 63119

Dear Mr. Osterman:

We are writing to you because on February 6-20, 2001, an investigator from the Food and Drug Administration (FDA) collected information that revealed a serious regulatory problem involving the product known as a Cranial Molding Helmet (Static), which is manufactured and distributed by your firm.

Under a United States Federal law, the Federal Food, Drug, and Cosmetic Act (Act), a Cranial Molding Helmet is considered to be a medical device because it is intended to treat a medical condition or to affect the structure or function of the body. A Cranial Molding Helmet device is classified as a cranial orthosis under Title 21 of the Code of Federal Regulations (21 CFR) 882.5970.

The investigation revealed that these devices are adulterated within the meaning of Section 501(h) of the Act, in that the methods used in, or the facilities or controls used for manufacturing, packing, storage, or installation are not in conformance with the Quality System regulation for medical devices, as specified in Title 21 of the Code of Federal Regulations, Part 820 (21 CFR 820) as follows:

1. Failure to establish a quality plan, management review procedures and quality audit procedures.
2. Failure to identify a management representative who is responsible for ensuring quality system requirements are adequate and implemented.
3. Failure to establish design control procedures.
4. Failure to implement adequate corrective and preventive action procedures.

5. Failure to establish process and document control procedures.
6. Failure to establish complaint-handling procedures that ensure complaints are evaluated to determine whether the complaint represents an event that is required to be reported under the FDA Medical Device Reporting (MDR) Regulation.

The law requires that manufacturers of medical devices obtain marketing clearance for their products from the Food and Drug Administration before they may offer them for sale. This helps protect the public health by ensuring that new medical devices are shown to be both safe and effective or substantially equivalent to other devices already legally marketed in this country.

Our records do not show that your firm obtained marketing clearance before it began offering your product for sale. The kind of information your firm needs to submit in order to obtain this clearance is described in the enclosed material entitled "Premarket Notification 510(k) Regulatory Requirements for Medical Devices". The FDA will evaluate this information and decide whether your product may be legally marketed.

Because your firm does not have marketing clearance from FDA, marketing a Cranial Molding Helmet is a violation of the law. In legal terms, the product is adulterated under Section 501(f)(1)(B) and misbranded under Section 502(o) of the Act. The product is adulterated under the Act because your firm did not obtain premarket approval based on information developed by your firm that shows the device is safe and effective. The product is misbranded under the Act because your firm did not submit information that shows its device is substantially equivalent to other devices that are legally marketed.

The law also requires under Section 510 (c) and (j) of the Act that your firm register and that your product be listed, respectively. Our records do not show that your firm has complied with either of the above requirements. Because your firm is not registered and your product is not listed, it is in violation of the law. In legal terms, the product is misbranded under Section 502(o) of the Act.

Instructions on how and where to register your establishment and list your devices may be found in 21 CFR 807. You may obtain more information, including registration and listing forms, by contacting FDA's Division of Small Manufacturer's Assistance at 800-638-2041 or at the Device Advice website (<http://www.fda.gov/cdrh/devadvice/>).

The law also requires under Section 519 of the Act that manufacturers, importers, and distributors of devices maintain such records, make such reports, and provide such

information as FDA by regulation reasonably requires to assure that a device is not adulterated or misbranded and to otherwise assure its safety and effectiveness. FDA promulgated under referenced Section 519, the Medical Device Reporting Regulation, 21 CFR 803. The investigation revealed that your firm has not met the requirements of 21 CFR 803. For example:

- Failure to develop, implement and maintain, written MDR procedures as required by 21 CFR 803.17.

Because your firm has not complied with the requirements of 21 CFR 803, your product is in violation of the law. In legal terms, the product is misbranded under Section 502(t)(2) of the Act.

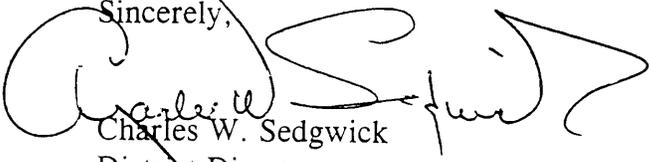
This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and the implementing regulations. The specific violations noted in this letter and in the Form FDA 483 issued to you at the conclusion of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems. You are responsible for investigating and determining the cause of the violations identified by FDA. If you determine your systems caused the problems, you must promptly initiate permanent corrective actions.

You should know that these serious violations of the law may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, seizing your product inventory, obtaining a court injunction against further marketing of the product, or assessing civil money penalties. Also, other Federal agencies are informed about the Warning Letters we issue, such as this one, so that they may consider this information when awarding government contracts. Additionally, no requests for Certificates to foreign governments will be approved until the violations related to the subject devices are corrected and verified.

It is necessary for you to take action on these matters now. Please notify this office, in writing, within fifteen (15) work days of receipt of this letter of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to identify and correct any underlying systems problems necessary to assure that similar violations will not recur. If corrective action cannot be completed within fifteen (15) working days, state the reason of the delay and the time within the corrections will be completed.

Mr. David Osterman, President  
Orthotic and Prosthetic Lab, Inc.  
April 9, 2001  
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Your response should be directed to Ralph J. Gray, Compliance Officer, at the above address.

Sincerely,  
  
Charles W. Sedgwick  
District Director  
Kansas City District

Enclosure: As stated