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DEPARTMENT OF HEALTH AND HUMAN SERVICE

Southwest Region

Food and Drug Administration
Denver District Office
Bldg. 20-Denver Federal Center
P.O. Box 25087
6th Avenue & Kipling Street
Denver, Colorado 80225-0087
Telephone: 303-236-3000
FAX: 303-236-3100

February 24. 2004

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Dr. Robert W. Christensen
President/CEO
TMJ Implants, Inc.
17301 W. Colfax Ave.
Suite 135
Golden, Colorado 80401

Ref. # - DEN-04-05

Dear Dr. Christensen:

An inspection of your firm located at 17301 W. Colfax Ave., Golden, Colorado was conducted between July 29-August 11, 2003, by Investigators Nicholas R. Nance and Patricia A. Cortez. This inspection determined that your firm manufactures fossa eminence prostheses, condyle prostheses and related items for temporomandibular joint (TMJ) implantation. These are devices as defined by section 201(h) of the Federal Food, Drug and Cosmetic Act (the Act).

The above-stated inspection revealed that your devices are misbranded within the meaning of section 502(t)(2) of the Act in that your firm failed or refused to furnish information to the Food and Drug Administration (FDA) as required by or under section 519 of the Act and the Medical Device Reporting (MDR) Regulation, Title 21, Code of Federal Regulations, Part 803 (21 CFR Part 803). Specifically, you failed to submit MDR reports to FDA after receiving information which reasonably suggested that one of your commercially distributed devices may have caused or contributed to a death or serious injury. Section 519(a)(2)(C) specifically defines the term "serious injury" to include an injury that necessitates medical or surgical intervention to preclude permanent impairment of a body function or permanent damage to a body structure.

MDR reports are required for the following event numbers, assigned by your complaint system, along with any other reports that you have received which reasonably suggest that one of your distributed devices may have caused or contributed to a death or serious injury or has malfunctioned and such device or similar device marketed by your firm would be likely to cause or contribute to a death or serious injury, if the malfunction were to recur.

XXXX Information in the complaint indicated that the left fossa and condyle prostheses were explanted. During surgery, it was noted that two screws were broken. Complaint follow-up notes that there was an off-label use in that the condylar devices were secured contrary to TMJ Implants "Instructions for Use". Your firm noted that there were X screws securing the condyle, and that the "Instructions for Use" recommend the use of XX screws per condyle. Your firm also noted that the screws were only placed at the bottom of the condyle, and there were no screws securing the top half of the condyle. Your firm indicates that the off-label use would have caused a sufficient amount of stress to break the screws. Your firm concluded that the failure of the screws was caused by the off-label use and not a deficiency of the device. This event is reportable as a serious injury MDR even though it was apparently caused by user error.

XXXX This complaint relates to a voluntary MedWatch report indicating there was medical intervention to preclude permanent impairment of a body function or body structure. After implantation of the device, the patient experienced significant swelling, increased pain and eventually decreased mobility. The patient was treated with XXXX different types of antibiotics. Blood work showed no sign of infection, but when the patient was taken off the antibiotics, swelling and pain worsened. XX months after surgery, it was still not possible to document an infection. Although your firm may have decided not to report this event as an MDR, the complaint file did not support a conclusion that a device-related adverse event did not occur. This event is reportable as a serious injury MDR.

XXXXXX Three MedWatch reports were combined into one complaint, XXX by your firm. The event description for MW1026641 states that the patient received a Christensen fossa and condyle which had to be explanted due to bone growth and the jaw fusing shut. The event description for MW1026649 states that the patient received a Christensen fossa bilaterally. One year later the patient began having grand mal seizures for the first time. The patient now has persistent migraine and facial swelling which has closed off the ear canal and causes black eyes. The screws from the fossa have loosened and have penetrated through to the zygomatic arch. The event description for MW1026650 states that the patient received X Christensen fossas. The patient has been experiencing headaches. The patient has also been experiencing pain when chewing and constant pain in the jaw joint area. Complaint XXX was submitted to your firm as MW1026765. The event description states that the patient received a total TMJ joint on the X side. The

patient's jaw now deviates to the X and there is a decrease in the mouth opening. The patient is experiencing pain, frequent sinus infections, and migraine headaches. In the complaint file, your firm indicated that it received insufficient information to investigate these complaints. Your firm indicated that it did not receive information concerning the date of surgery; the device model number or lot number; or the name of the patient for these events. Your firm concluded that, because there is no indication from a health professional for complaints that a device failure occurred, the events are not MDR reportable. However, the information in the event descriptions reasonably suggests that your firm's device may have caused or contributed to the reported events. These MedWatch reports should have been submitted as serious injury MDR's.

XXXX Information in the complaint indicates that there was metal fatigue fracture of the X glenoid fossa prosthesis. An MRI examination revealed recurrence of ankylosis and heterotopic bone formation in the X TM joint arising off the mandibular condyle and encompassing the glenoid fossa prosthesis. The patient had been involved in XXX XXX X X. This event is reportable as a serious injury MDR.

XXXX The complaint states that a postoperative diagnosis was reported as bilateral temporomandibular joint alloplastic prosthesis failure. The X condylar prosthesis screws were all loose and out of the bone. The X condylar prosthesis was malpositioned. Both condylar prostheses were eroding into the temporal bone. There is no information on the complaint form indicating an MDR reportability decision nor is the MDR Evaluation Checklist form completed even though the file was closed 7/17/03. This event is reportable as a serious injury MDR.

XXXX Information in the operative report related to explantation of the device indicates that the patient had degenerative disease including inflammation which contributed to the wear of the prosthesis, as well as bone screw loosening in the X condyle component which may have contributed to the patient's pain. This event is reportable as a serious injury MDR.

XXXX The surgeon indicated that there was an explant of the prosthesis due to bilateral TMJ pain. Your firm did not obtain more information from the physician regarding the surgery. Unless your firm obtains additional information supporting the conclusion that a device related adverse event did not occur, this event is reportable as a serious injury MDR.

XXXX The information in the complaint indicates that the XX fossa-eminence prosthesis was removed because the condyle was deformed and arthritic clinically. The patient's history indicates continuing pain, swelling and restricted opening since fossa arthroplasty with the Christensen device. The complaint also states "This is continuation of disease." This record does not support a conclusion that a device related adverse event did not occur, and this event is reportable as a serious injury MDR.

[redacted] Information in the complaint indicates that the patient had a history of [redacted] and the [redacted] prosthesis was explanted due to pain, infection, inflammation and limited opening. The [redacted] side histologically showed localized foreign body reaction in soft overlying tissues with recurrent formation of salivary fistula. Several mobile screws in the [redacted] fossa-eminence prosthesis area were noted at explant. This event is reportable as a serious injury MDR.

[redacted] Information in the complaint indicates that the [redacted] side prosthesis was removed due to infection. Information from the physician indicates that the [redacted] prosthesis perforated from the posterior of the fossa-eminence, through the bone of the external auditory canal, and into the external auditory canal cartilage above the tympanic membrane. This event is reportable as a serious injury MDR.

[redacted] Information in the complaint indicates that bilateral total prostheses were removed in order to clear up an infection and perforation between the external auditory canal and joint space. At operation, the screws in the condylar portion of the [redacted] hand side were all loose except for the inferior two screws, which were marginally tight. One of the screws was completely lifted out of its hole in the condylar portion of the prosthesis. The tissue showed moderate acute and chronic inflammation and fibrinoid necrosis. This event is reportable as a serious injury MDR.

[redacted] Complaint information indicates prosthesis was removed due to loose hardware and infection. The physician noted that longer screws were needed for the explanted device. This event is reportable as a serious injury MDR.

[redacted] Complaint information indicates the reason for explant was pain, limited opening, swelling and malocclusion. At operation, the [redacted] fossa was found to be eroded and the cranial was loose. The [redacted] condyle was loosening and there was dislocation of the fossa implant. The [redacted] condyle was loose. The screws were also loose. Tissue from the mandibular joints was chronically inflamed with fibrosis. The surgeon noted that with abnormal anatomy the implanted devices became unstable. This event is reportable as a serious injury MDR.

[redacted] According to the complaint information, surgery was performed to replace fossa screws due to improper screw fit. There is no information in the complaint regarding reasons for the improper screw fit including the possibility of user error. This event is reportable as a serious injury MDR.

[redacted] The complaint information indicates that a [redacted] fossa-eminence prosthesis was explanted. The reason for the explant surgery was a failed fossa and adhesions. It was noted during the operation that there was marked resorption to [redacted] condylar head. The posterior and third screws were found to be loose and somewhat backed out. There also appeared to be heterotropic bone along these areas as well. The postoperative diagnosis was stated to be

progressive degenerative joint disease of the left TMJ. This event is reportable as a serious injury MDR.

XXX Four MedWatch complaints were combined into one complaint by your firm. The event description for MW1027888 states that patient is currently experiencing foreign body reaction to joints. The patient's symptoms include ear pain, ear ringing, dizziness, vertigo, headaches, swelling and tenderness around joint area and neck and shoulder pain. The patient also stated that the implant screws may be loose. The event description for MW1027889 states that the patient is having problems with migraine headaches and jaw pain and there is limited jaw opening. The patient states that pain has been worse since the device was implanted. The event description for MW1027890 states that implants were removed after XXX due to ear pain and fibrosis and osteophytes were discovered during the explant surgery. The patient was told by the surgeon that the implants didn't take. The condyles were reconstructed because of huge bone spurs and masses of fibrosis. The patient continues to experience headaches and ear pain and ringing. The patient is taking medication to control the pain. The event description for MW1027891 states there was a fossa placement and that the joint is sticking and the patient is experiencing pain and migraine headaches. The patient states that the doctors had to cut the bone away and then did a one time radiation treatment to help prevent bone from growing back. Even though the devices in these events were not returned to the manufacturer and the events were not submitted by a health professional, the information in these four MedWatch reports reasonably suggests that your firm's devices may have contributed to the reported events. These MedWatch reports should have been submitted as four individual serious injury MDRs.

XXX The complaint was submitted to your firm as MW1028047. The information in the event description indicated that Christensen metal on metal total TMJ's were placed bilaterally. The patient developed severe, disabling headaches, muscle pain in and around the implant, and serious tenderness in and around the implant area. Dizziness, nausea and neck and shoulder pain accompany the problem. Chewing, speaking, or any bump on the chin exacerbates the problems. The patient is on anti-inflammatory and medications for chronic pain which help. The patient believes that the situation appears to be attributable to foreign body reaction or other problems with the implant. The reporter did not request anonymity. Your complaint file states that there is no information from a health professional to indicate a device failure or that the device caused or contributed to the event. The information in the event description is insufficient to support a conclusion that a device related adverse event did not occur. This event is reportable as a serious injury MDR.

XXX Your firm's devices were explanted due to pain and swelling. On operation it was found that the acrylic condyle appeared to be worn and flattened and granulation tissue surrounded the condyle. The surgeon felt that a couple of

large submandibular nodes were concurrent with an inflammatory reaction to the wear of the device. The explanting surgeon believed the device caused or contributed to the need for the explant. This event is reportable as a serious injury MDR.

XXX The limited information in the complaint indicates that the patient has ankylosis and cannot open more than 12mm. The right prostheses were removed and replaced. The information in the event description is insufficient to support a conclusion that a device related adverse event did not occur. This event is reportable as a serious injury MDR.

XXX The limited information in the complaint indicates that the physician treated X post operation infections in X different patients. The information in the event description is insufficient to support a conclusion that a device related adverse event did not occur. This complaint should have been submitted as two serious injury MDRs.

XXX According to the information in the event text, the surgeon implanted the Fossa-Eminence sizers instead of the actual devices. Your firm advised the physician to remove the sizers which was done the next day and the correct prostheses were implanted. This event is the result of user error. This event is reportable as a serious injury MDR.

Written MDR reports for the above listed incidents should be submitted within 15 working days of receipt of this letter. If these reports cannot be submitted within that time period, you should provide this office with a response which indicates when the reports will be submitted. The MDR reports should reference this Warning Letter and be directed to:

Ms. Victoria A. Schmid
Division of Surveillance Systems (HFZ-533)
Office of Surveillance and Biometrics
Food and Drug Administration
1350 Piccard Drive
Rockville, Maryland 20850

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to assure adherence with each requirement of the regulations, as well as other requirements of the Act.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice. These actions include, but are not limited to seizure, injunction, and/or civil penalties.

Federal agencies are advised of the issuance of all warning letters regarding medical devices so that they may take this information into account when considering the award of contracts.

We could not properly evaluate one other adverse event in which an injury may have resulted from a device malfunction, because there was insufficient information to make a determination of MDR reportability. In event XXX, the only information found in the complaint was that XXXX fossa eminences and XXXX condyles were explanted, and that they were replaced with other prostheses on XX. There is no information regarding the reason for the explants. The device evaluation by your firm notes wear on all of the returned prostheses. There is insufficient information in the complaint to support a conclusion that a device-related adverse event did not occur.

FDA has communicated similar concerns regarding your firm's failure to submit MDR's in the letters of October 23, 2002, and March 13 and April 28, 2003. It appears that you have had difficulty understanding how to implement the requirements in the MDR regulation and have therefore failed to submit MDR's. In your August 25, 2003, response concerning our investigator's observation #2 regarding MDR reporting on the form FDA 483, your firm agreed to reassess your MDR reporting. However, we note that you have not yet filed MDR's for these events.

Your August 25, 2003, response concerning the observations on the Inspectional Observations, form FDA 483, regarding the Quality System regulation deviations appears to be adequate.

Please notify this office in writing within fifteen (15) working 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 prevent the recurrence of similar violations. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time frame within which the correction will be completed.

Your reply should be sent to the Food and Drug Administration, Denver District Office, Attention: H. Tom Warwick, Compliance Officer. Please provide Mr. Warwick with a copy of each MDR report sent to Ms. Victoria Schmid.

Sincerely,

Susan J. Miller for

B. Belinda Collins
District Director