K023572

JAN 1 3 2003

Section E – 510(k) Summary

1. **Applicant:** Michael J. Davidson, MPH, CPO
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Submission Correspondent:
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2. **Trade name:** LLUMC Cranial Remolding Helmet
Common name: Cranial Orthosis
Classification: orthosis, cranial
882.5970
MVA

3. **Predicate Device:** Clarren Helmet
K003035
MVA

4. **Description of Device:** The LLUMC Cranial Remolding Helmet is a cranial orthosis used to treat children 3-18 months of age for moderate to severe non-synostotic plagiocephaly, brachycephally, and scaphocephally. The LLUMC Cranial Remolding Helmet is fabricated from a cast impression of the infant's cranium, taken by a certified orthotist (CO). The negative cast impression is converted by the CO into a positive impression and rectified into the desired corrected shape. The helmet is then formed over the corrected positive mold by a registered orthotic technician (RTO). A 1/4" polyethylene form (Volara) is used as an interface (liner) material, and 3/16" sheet of polyethylene plastic is used as the outer shell. The helmet is then trimmed by the RTO, as necessary to not obstruct the infant's vision, hearing, ability to breathe or restrict movement of the head and neck. Ventilation holes are added to reduce heat retention. The CO fits the Cranial Remolding Helmet to the infant. The Cranial Remolding Helmet provides a gentle pressure over the

prominent areas of the cranium in an effort to slow the growth in these areas. Voids are provided in an effort to encourage growth over the flat areas and reduce deformity. The infant is then evaluated monthly by the CO to monitor growth and insure that a precise fit is maintained. Adjustments are made to the device as needed to accommodate growth and/or optimize the function of the helmet.

5. **Intended Use:** The Cranial Remolding Helmet is a cranial orthosis that is intended for moderate to severe non-synostotic plagiocephaly, brachycephally, and scaphocephaly in patients of 3-18 months of age. It is intended to provide gentle pressure over prominent areas of the infant's cranium to slow the growth in these areas in order to improve cranial symmetry and/or shape. The Cranial Remolding Helmet is provided by a Certified Orthotist (CO) solely on the order (prescription) of a licensed physician and fabricated by a Registered Orthotic Technician (RTO).

6. **Technological Characteristics:** The LLUMC Cranial Remolding Helmet has the same technological characteristics as the predicate device, the Clarren Helmet, K003035. Both cranial helmets are custom-made to the requirements of each individual infant. The assembly of both helmets begins with creating a negative cast impression of the infant's head, which is converted to a plaster model. The plaster model is then modified so that the cranial helmet will fit snugly over prominent areas to provide gentle pressure, and will have open areas (voids) to encourage growth over the flattened portion of the skull.

   Each cranial helmet is formed over the modified plastic mold. Each helmet has a soft foam lining and a rigid thermoplastic shell which controls and directs cranial growth.

7. **Biocompatibility:** Information is provided on the biocompatability of the skin-contacting materials.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Rehabilitation Institute, Loma Linda
University Medical Center
C/O Lynn D. Fleisher, Ph.D., J.D.
Sidley Austin Brown & Wood
Bank One Plaza
10 S. Dearborn Street
Chicago, Illinois 60603

Re: K023572
Trade/Device Name: Loma Linda University Medical Center (LLUMC) Cranial Remolding Helmet
Regulation Number: 21 CFR 882.5970
Regulation Name: Cranial Orthosis
Regulatory Class: Class II
Product Code: MVA
Dated: October 23, 2002
Received: October 24, 2002

Dear Dr. Fleisher:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

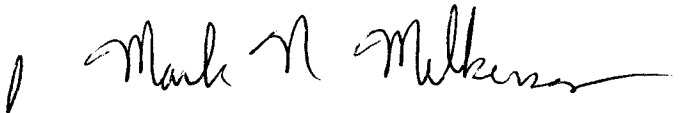
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section D – Statement of Indications for Use

Device Name: LLUMC Cranial Remolding Helmet
510(k) Number: Not known

Indications for use: The LLUMC Cranial Remolding Helmet is a cranial orthosis that is intended for use on infants from three to eighteen months of age with moderate to severe non-synostotic positional plagiocephaly, including infants with plagiocephalic-, brachycephalic- and scaphocephalic-shaped heads. The device is intended to apply pressure to prominent regions of an infant's cranium in order to improve cranial symmetry and/or shape. It is indicated for prescription use.

Contraindications: synostosis and hydrocephalus

for Mark N Melkerson

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K023572