OCT 2 9 2001

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510(k) Summary

Submitter
Children's Hospital
8200 Dodge Street
Omaha, NE 68114-4113

Telephone: (402) 955-4173
Fax: (402) 955-6030

Date Prepared
October 17, 2001

Trade Name
None

Common Name
Cranial Orthosis

Predicate Device
Gillette Children's Specialty Healthcare - CranioCap™

Device Description
The Children's Hospital cranial helmet is a cranial orthosis for the treatment of deformational plagiocephaly. It is a lightweight, semi-rigid plastic helmet with a foam lining. Each helmet is assembled individually, with some areas that fit snugly to the child's head, and with other recessed areas. As the child's brain grows, the skull is slowly reshaped and rounded by growing into the recessed areas.

Intended Use
The Children's Hospital cranial helmet is intended to apply passive pressure to prominent regions of an infant's cranium in order to improve cranial symmetry and/or shape in 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.

Technological Characteristics
Each child with deformational plagiocephaly has a unique skull shape and size, with varying areas of the skull affected. Therefore, each cranial helmet is custom-made. The assembly of the cranial helmet begins with creating a negative impression of the head. From this a plaster model of the head is made. The plastic helmet with its foam lining is made using the plaster model, and is designed to fit snugly in some areas and is recessed in others. As the child's brain grows, the skull is slowly reshaped and rounded by growing into the recessed areas.

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Summary of Studies

Information was provided on the biocompatibility of the skin-contacting materials and on the safety and effectiveness of the helmet.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 2 9 2001

Children's Hospital
c/o Ms. Connie Ficklin
Regulatory and Clinical Research Institute, Inc.
5353 Wayzata Boulevard, Suite 505
Minneapolis, Minnesota 55416

Re: K013458
Trade/Device Name: Cranial Helmet
Regulation Number: 882.5970
Regulation Name: Cranial orthosis
Regulatory Class: II
Product Code: MVA
Dated: October 17, 2001
Received: October 18, 2001

Dear Ms. Ficklin:

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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), 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

Indications for Use

510(k) Number (if known): K013458

Device Name: Cranial Helmet

Indications for Use: The Children's Hospital cranial helmet is intended to apply passive pressure to prominent regions of an infant's cranium in order to improve cranial symmetry and/or shape in 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.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use_____ OR Over-The-Counter Use_____

(Per 21 CFR 801.109)

for Mark N Milhoan

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

510(k) Number K013458