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510(k) Summary

The following summary is provided in pursuant to Section 513 of the Federal Food, Drug and Cosmetic Act.

1. **DATE PREPARED**

   December 27, 2007

2. **APPLICANT INFORMATION**

Hanger Prosthetics & Orthotics, Inc.
2 Bethesda Metro Center
Bethesda, MD 20814

JAN - 9 2008

Contact Person:

Kaia Busch C.P.O.

(206). 923.0476 (telephone)
(206).923.0366 (facsimile)

Outside Regulatory Counsel:

Ivan J. Wasserman
Manatt, Phelps, & Phillips, LLP
700 12th Street, NW
Suite 1100
Washington, D.C. 20005
Tel. (202) 585-6529

3. **DEVICE NAME**

Proprietary Name:	Hanger Cranial Band™
Common/Usual Name:	Cranial Orthosis
Classification Names and numbers:	Cranial Orthosis, laser scan, OAN Cranial Orthosis, MVA 21 CFR § 882.5970

4. DEVICE DESCRIPTION AND INTENDED USE

The Hanger Cranial Band™ is a thermoplastic helmet prepared with USP Class VI materials; a polypropylene or polypropylene-polyethylene copolymer outer shell. The Hanger Cranial Band™ was initially cleared on December 8, 2000, under 510(k) K001669. This submission provides for the use of a hand held 3-dimensional laser scanner to acquire accurate measurements and a CAD/CAM system to fabricate the orthosis.

A medium density polyethylene foam inner lining is thermo-bonded to this shell. The device is custom fabricated for individual patients by obtaining accurate measurements via a hand held 3-dimensional laser scanner. Clinical measurements of the infant's cranium are taken from the digital file. The addition of digital imaging allows for increased clinical accuracy and objective clinical documentation. The scan is then modified utilizing a CAD/CAM technology package. The 3-dimensional cranial scan is modified utilizing computer aided design tools to add or remove material, increase or decrease the circumference of model to aid in fit and functionality of the cranial band/orthosis. Modifications include but are not limited to: relief areas opposite of cranial bossing, circumference modifications for growth and remolding, suspension, and rotational modifications. The modified file is then emailed to the central manufacturing facility for fabrication and delivery. The modified file measurements are validated and a positive model carved for fabrication.

The carved model is evaluated for clinical accuracy and used to fabricate the definitive orthosis. The definitive Hanger Cranial Orthosis is processed through a quality control check list to ensure clinical accuracy, appropriate fabrication techniques, and quality assurance. The Hanger Cranial Band is sent to the practitioner for patient fit and delivery. A digital record of each patient scan and modifications will be maintained on file at Hanger for each patient.

Indications for Use:

Intended for medical purposes to apply static or gentle pressure to prominent regions of an infant's cranium to improve cranial symmetry or shape. To treat infants from three to eighteen months of age with moderate to severe non-synostotic positional plagiocephaly, including plagiocephalic-, brachycephalic-, scaphocephalic-shaped heads.

Contraindications for Use:

Infants with synostosis and or hydrocephalus

5. PREDICATE DEVICE

a. K014012 (Cranial Technologies the Doc Band)

b. Substantial Equivalence Comparison

Hanger's device is custom fabricated for individual patients by obtaining accurate measurements via a hand held 3-dimensional laser scanner.

Clinical measurements of the infant's cranium are taken from the digital file. The addition of digital imaging allows for increased clinical accuracy and objective clinical documentation. The scan is then modified utilizing a CAD/CAM technology package. The 3-dimensional cranial scan is modified utilizing computer aided design tools to add or remove material, increase or decrease the circumference of model to aid in fit and functionality of the cranial band/orthosis. Modifications include but are not limited to: relief areas opposite of cranial bossing, circumference modifications for growth and remolding, suspension, and rotational modifications. The modified file is then emailed to the central manufacturing facility for fabrication and delivery. The modified file measurements are validated and a positive model carved for fabrication. The carved model is evaluated for clinical accuracy and used to fabricate the definitive orthosis. The definitive Hanger Cranial Orthosis is processed through a quality control check list to ensure clinical accuracy, appropriate fabrication techniques, and quality assurance. The Hanger Cranial Band is sent to the practitioner for patient fit and delivery. A digital record of each patient scan and modifications will be maintained on file at Hanger for each patient.

Cranial Technologies uses a different system, the C3D Cranial Imaging System to obtain patient head shape measurements and a different CAD/CAM System to create a model used in fabricating the device.

6. PERFORMANCE CHARACTERISTIC SUMMARY

There has been no change to the performance characteristics of the device system.

7. TECHNOLOGICAL CHARACTERISTICS

There has been no change to the fundamental scientific technology.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN - 9 2008

Manatt, Phelps & Phillips
% Mr. Ivan J. Wasserman
700 12th Street, NW
Washington, DC 20005

Re: K072566
Trade/Device Name: Hanger Cranial Band
Regulation Number: 21 CFR 882.5970
Regulation Name: Cranial orthosis
Regulatory Class: II
Product Code: OAN, MVA
Dated: January 3, 2008
Received: January 3, 2008

Dear Mr. Wasserman:

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
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): K072566

Device Name: Hanger Cranial Band™

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Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

(Division Sign-Off) Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of General, Restorative, and Neurological Devices

510(k) Number K072566