K013719

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

FEB 0 5 2002

I. Submitter: Dr. James H. Campbell, Becker Orthopedic, Troy, Michigan, Ph: 248-588-6961

II. Classification: Class II.

III. Common or usual name: Cranial orthosis

IV. Proprietary Name: BeckerBand™ Cranial Remolding Orthosis

IV. Registration No.: 1824252

V. Classification Name: Cranial Orthosis, Code MVA, CFR 882.5970

VI. Performance standards: None, Special Controls required.

VII. Description: The BeckerBand™ is a thermoplastic helmet prepared with USP Class VI materials, consisting of a polypropylene or polypropylene-polyethylene copolymer outer shell. To this shell is thermobonded a medium density polyethylene foam inner lining. The device is fabricated by taking a plaster-of-paris impression of the infant's head.This impression is filled with a plaster slurry to create a positive mold of the skull. The deformity is corrected to the desired configuration by building the mold up in selected areas with molding material. This corrected mold serves as a template for preparation of the BeckerBand™ orthosis. The completed device applies gentle pressure to the elevated areas of the skull while leaving space for cranial growth in the depressed regions.

VIII. Labels and Labeling: Labels and Instructions for Use are provided including precautions, and materials required by the special controls to which this product is subject.

IX. Instructions for Use: For treatment of positional plagiocephaly.

X. Substantial Equivalence: The BeckerBand™ is substantially equivalent to the classified device (Cranial Orthosis), to the Doc Band device of Cranial Technology, cleared under K-964992, the OPI Band cleared by Orthomerica Products, Inc. in K-001167, the Craniocap cleared by Gilette Childrens., in K-000861, and the Cranial Molding Orthosis cleared by Orthotic Solutions in K-010273. The devices are made of similar if not identical materials widely used in the orthotic industry, by well-known technology, under carefully controlled conditions. The BeckerBand™ complies with the Class II special controls established for this device in the classification process to provide assurance of safety and effectiveness.
The "510(k) Substantial Equivalence Decision-making Process (Detailed) from ODE Guidance Memorandum #86-3 was followed.

XI. Clinical Discussion and Literature: A comprehensive review of the literature was provided.

XII. Indications for Use
Intended for medical purposes to apply 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 or hydrocephalus.

(End of Summary)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 0 5 2002

James H. Campbell, Ph.D.
Director, Product Development
Engineering & Tech Services
Becker Orthopedic Appliance Company
635 Executive Dr.
Troy, Michigan 48083

Re: K013719
Trade/Device Name: BeckerBand™ Cranial Remolding Orthosis
Regulation Number: 21 CFR 890.5970
Regulation Name: Cranial Orthosis
Regulatory Class: Class II
Product Code: MVA
Dated: November 3, 2001
Received: November 8, 2001

Dear Dr. Campbell:

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 Mark N Melkerson

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: NA K013719

Device Name: BeckerBand™

Indications for Use:

Intended for medical purposes to apply 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.

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(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) (Optional Format 1-2-96)

for Mark N Milhern

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

510(k) Number K013719 12/4/02