K042385

DEC 17 2004

510(k) SUMMARY

Cranial Technologies, Inc.'s DOC Band Post-Op™

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

Cranial Technologies, Inc.
1395 West Auto Drive
Tempe, AZ 85284
Phone: (480) 505-1840
Facsimile: (480) 505-1844

Contact Person: Timothy R. Littlefield

Date Prepared: August 5, 2004

Name of Device and Name/Address of Sponsor

DOC Band-PostOp™

Cranial Technologies, Inc.
1395 West Auto Drive
Tempe, AZ 85284
Phone: (480) 505-1840
Facsimile: (480) 505-1844

Common or Usual Name

Cranial Remodeling Band, Cranial Helmet, Molding Helmet

Classification Name

Cranial Orthosis, 21 C.F.R. § 882.5970

Predicate Devices

Cranial Technologies, Inc.'s DOC Band (K964992)

Intended Use / Indications for Use

This DOC Band-PostOp is intended for medical purposes to apply pressure to prominent regions of an infant's cranium to improve cranial symmetry or shape. The device is indicated for adjunctive use for infants from three to eighteen months of age whose synostosis has been surgically corrected, but who still have moderate to severe cranial deformities including plagiocephalic-, brachycephalic-, and scaphocephalic-shaped heads.

The device is contraindicated for use on infants with craniosynostosis or hydrocephalus.

Technological Characteristics

The DOC Band-PostOp consists of a plastic band, a fastener with Velcro strap, and, in some models, a strut to hold height at the top of the head.

Substantial Equivalence

The DOC Band-PostOp has the same intended uses, technological characteristics, and principles of operation as its predicate device, the cleared DOC Band, and very similar indications. The new indication for use does not raise any new questions of safety or effectiveness. Furthermore, clinical data demonstrate that the DOC Band-PostOp, as indicated for use post-operatively, in the absence of craniosynostosis, is as safe and effective as the DOC Band. Thus, the DOC Band-PostOp is substantially equivalent. A summary of substantial equivalence between the devices is provided in the following Substantial Equivalence Chart.

CRANIAL TECHNOLOGIES, INC.'S
DOC BAND-POSTOP
SUBSTANTIAL EQUIVALENCE CHART

	DOC Band-PostOp™	DOC Band® (K964992)
Intended Use	The device is intended for medical purposes to apply pressure to prominent regions of an infant's cranium to improve cranial symmetry or shape.	The device is intended for medical purposes to apply pressure to prominent regions of an infant's cranium to improve cranial symmetry or shape.
Indications for Use	Indicated "for adjunctive use in infants from three to eighteen months of age whose synostosis has been surgically corrected, but who still have moderate to severe cranial deformities including plagiocephalic-, brachycephalic-, or scaphocephalic-shaped heads."	Indicated "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	Infants with craniosynostosis or hydrocephalus.	Infants with craniosynostosis or hydrocephalus.
Technological Characteristics		
	Band (constructed of USP Class VI semi-rigid polypropylene-polyethylene copolymer outer surface thermobonded to a medium density polyethylene foam (Pelite) inner lining) Plastic and Steel Fastener with Velcro Strap Strut (in Bi-Cal design only) Elastic Bands (in Bi-Cal design only)	Band constructed of USP Class VI semi-rigid polypropylene-polyethylene copolymer outer surface thermobonded to a medium density polyethylene foam (Pelite) inner lining) Plastic and Steel Fastener with Velcro Strap Elastic Bands (in Bi-Cal design only)
Biocompatibility	Yes.	Yes.
Sterilization	Not provided sterile.	Not provided sterile.
Standards with which the Device Complies	No performance standards apply. The device complies with FDA's special controls for cranial orthosis devices.	No performance standards apply. The device complies with FDA's special controls for cranial orthosis devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 17 2004

Mr. Timothy R. Littlefield, MS
Vice President
Cranial Technologies, Inc.
1395 West Auto Drive
Tempe, Arizona 85284

Re: K042385
Trade/Device Name: DOC Band-PostOp™
Regulation Number: 21 CFR 882.5970
Regulation Name: Cranial Orthosis
Regulatory Class: II
Product Code: MVA
Dated: December 9, 2004
Received: December 10, 2004

Dear Mr. Littlefield:

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.

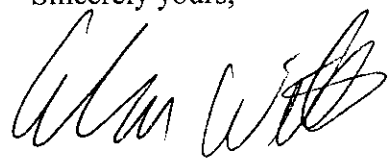
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



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 Statement

510(k) Number (if known): K042385

Device Name: DOC Band-PostOp™

Indications for Use:

This DOC Band-PostOp is intended for medical purposes to apply pressure to prominent regions of an infant's cranium to improve cranial symmetry or shape. The device is indicated for adjunctive use for infants from three to eighteen months of age whose synostosis has been surgically corrected, but who still have moderate to severe cranial deformities including plagiocephalic-, brachycephalic-, and scaphocephalic-shaped heads.

The device is contraindicated for use on infants with craniosynostosis or hydrocephalus.

Prescription Use __X__ AND/OR Over-The-Counter Use____
(Part 21 C.F.R. 801 Subpart D) (21 C.F.R. 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

Page ____ of ____

510(k) Number K042385