K081787 1/2

JAN 27 2009

510(k) Summary

The following safety and effectiveness summary has been prepared pursuant to requirement for 510(k) summaries specified in 21CFR 807.92(a).

807.92(a)(1)

Submitter Information

BioSculptor Corporation
2480 West 82nd Street, #8
Bay 1A
Hialeah, Florida 33016

Phone: (305) 556-5815
Fax: (305) 823-8304
Contact: Mark Mazloff

Date: June 18, 2008

807.92(a)(2)

Proprietary Name:	CAMLab Cranial Orthosis Helmet
Common or Usual Name:	Cranial Orthosis Helmet
Regulation Number:	21 CFR 882.5970
Classification Name(s):	Orthosis, Cranial Laser Scan Cranial Orthosis
Classification Code:	OAN
Secondary Classification Code:	MVA

807.92(a)(3)

Predicated Device(s)

Orthomerica	STARband	K011350	Classified under 21 CFR 882.570

Additional substantial equivalence information is provided in the following Substantial Equivalence Comparison Table.

807.92(a)(4)

Device Description

The CAMLab Cranial Orthosis Helmet is intended for use on infants from 3 to 18 months of age with moderate to severe nonsynostotic positional plagiocephaly, including infants with plagiocephalic-, brachycephalic-, and scaphocephalic-shaped heads. The device is intended for medical purposes to apply pressure to prominent regions of an infant's cranium in order to improve cranial symmetry and/or shape. This orthosis is only available if prescribed by a physician.

The initial geometry of the patient is acquired from either laser scanned measurements using the BioScanner (a.k.a. Polhemus Fastscan handheld laser scanner) or via traditional casting methods. If a cast is taken, the cast will be scanned with the BioScanner as well.

The resulting three dimensional model along with a digital order form and any other pertinent information is then sent to BioSculptor Corporation via email or secured internet application. Utilizing this information, the BioSculptor CAD/CAM system will then create a positive mold representative of the patient scan. This positive model will then be used to create the orthosis.

Each orthosis consist of a plastic outer shell, a foam inner shell, a strap and fastener to secure the orthosis. The practitioner modifies the orthosis to achieve an accurate fit and monitors the progress to ensure that no adverse effects occur.

807.92(a)(5)

Intended Use(s)

The CAMLab Cranial Orthosis Helmet is intended for use on infants from 3 to 18 months of age with moderate to severe nonsynostotic positional plagiocephaly, including infants with plagiocephalic-, brachycephalic-, and scaphocephalic-shaped heads. The device is intended for medical purposes to apply pressure to prominent regions of an infant's cranium in order to improve cranial symmetry and/or shape.

807.92(a)(6)

Substantial Equivalence Comparison Table

	Orthomerica STARband Cranial Orthosis K011350	CAMLab Cranial Orthosis Helmet (This submission)
Indications for Use	Treatment of abnormal infant head shape (positional/deformational plagiocephaly)	Treatment of abnormal infant head shape (positional/deformational plagiocephaly
Materials	Copolymer plastic/closed cell polyethylene foam/Velcro strap	Copolymer plastic/closed cell polyethylene foam/Velcro strap
Clinical Population	Infants age 3-18 months	Infants age 3-18 months
Daily Wear Time	23 hrs./day	23 hrs./day
Average Time to Effectiveness (patients age 3-7 months)	2-4 months	2-4 months
Contradictions for Use	Craniosynostosis/Hydrocephalus	Craniosynostosis/Hydrocephalus
Method of Manufacture	Custom from mold using a laser scanner, CAD/CAM system and 5-axis router machine	Custom from mold using a laser scanner, CAD/CAM system and 5-axis router machine

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 27 2009

BioSculptor Corporation
% Mr. Mark Mazloff
2480 West 82nd Street, #8
Hialeah, Florida 33016

Re: K081787
Trade/Device Name: CAMLab Cranial Orthosis Helmet
Regulation Number: 21 CFR 882.5970
Regulation Name: Cranial orthosis
Regulatory Class: II
Product Code: OAN, MVA
Dated: January 6, 2009
Received: January 7, 2009

Dear Mr. Mazloff:

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 toll-free number (800) 638-2041 or (240) 276-3150 or the 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 STATEMENT

Applicant: BioSculptor Corporation

510(k) Number (if known): K081787

Device Name: CAMLab Cranial Orthosis Helmet

Indications for Use:

The CAMLab Cranial Orthosis Helmet is intended for use on infants from 3 to 18 months of age with moderate to severe nonsynostotic positional plagiocephaly, including infants with plagiocephalic-, brachycephalic-, and scaphocephalic-shaped heads. The device is intended for medical purposes to apply pressure to prominent regions of an infant's cranium in order to improve cranial symmetry and/or shape.

(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 _____

(Per 21 CFR,801.109)

(Optional Format 1-2-96)

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

510(k) Number K081787