K012804

JAN 17 2002

510 (k) Section – E-1

510(k) Summary

Application Date: August 14, 2001

Applicant Name: Scott E. Allen, C.P. Phone No: (801)364-3100
Address: 50 South 900 East #1
Salt Lake City, UT 84102 Fax No: (801)575-5462

Contact Person Scott E. Allen, C.P.
Trade Name: Plagiocephalic Applied Pressure Orthosis P.A.P. Orthosis
Common Name: Orthosis
Classification: Cranial Orthosis

The P.A.P. is similar in function and purpose to both the D.O.C. band, manufactured by cranial Technologies Inc. and is classified by the FDA as a cranial Orthosis #510 (k) K964992. And the STARband, manufactured by Orthomerica and is classified by the FDA as a cranial Orthosis #510 (k) k001167. It is a proprietary transparent ionomer based thermoplastic molded orthosis extended for medial purposes to apply pressure to the prominent regions of an infants cranium to improve cranial symmetry and to shape. This orthosis is used to treat infants from three to eighteen months of age with a diagnosis of moderate to severe non-synastolic positional Plagiocephaly. The D.O.C. band (K964992) is a band that goes around the infants head made from copolymer plastic lined with a single thickness of aliplast foam. The intended use is to treat moderate to severe nonsynostotic positional plagiocephaly. The STARband (K001167) is more encompassing than the D.O.C. band it goes around the infant's head made from copolymer plastic lined with one or more pieces of aliplast foam. The intended use is to treat moderate to severe nonsynostotic positional Plagiocephaly.The P.A.P orthosis more completely encompasses the cranium with clear copolymer plastic. The intended use is the same as the D.O.C. and STARband orthoses. s. This material has been widely used in upper and lower extremity orthotics, body jackets, and flexible prosthetic sockets.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 17 2002

Scott E. Allen
President
Personal Performance Medical Corp.
Fit-Well Prosthetic and Orthotic Center
50 South, 900 East #1
Salt Lake City, UT 84102

Re: K012804
Trade/Device Name: Plagiocephalic Applied Pressure (P.A.P.) Orthosis
Regulation Number: 21 CFR 890.5970
Regulation Name: Cranial Orthosis
Regulatory Class: Class II
Product Code: MVA
Dated: October 20, 2001
Received: October 24, 2001

Dear Mr. Allen:

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

Applicant: Scott E. Allen C.P.

510(k) Number (if known): K012804

Device Name: Plagiocephalic Applied Pressure Orthosis (P.A.P. orthosis)

The indications for use would include infants from three to eighteen months of age to be diagnosed with Plagiocephalic, Brachycephalic, or scaphocephalic shaped heads by a medical physician. The purpose of the P.A.P. Orthosis is to apply pressure to prominent regions of an infant's cranium in order to improve cranial symmetry and/or shape. This P.A.P. therapy must be prescribed by a physician in writing indicating the need for cranial positional molding due to the above diagnoses. The device is indicated to treat moderate to severe nonsynostotic positional plagiocephaly.

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

Concurrence of CDHR, Office of Device Evaluation (ODE)

for Mark N Milhoan

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

510(k) Number K012804

Prescription Use ✓ OR Over-The-Counter Use _____

(Per 21 CFR 801.109)

(Optional Format 1-2-96)