K012007

SEP 1 9 2001

APPENDIX E

510(k) SUMMARY

RHS Helmet

Restorative Health Services, Inc.

This 510(k) summary of safety and effectiveness for the Cranial Helmet is submitted in accordance with the requirements of SMDA and follows Office of Device Evaluation guidance concerning the organization and content of a 510(k) summary.

Applicant:	Restorative Health Services, Inc. DBA Dillard Prosthetics-Orthotics
Address:	311 18th Avenue North Nashville, TN 37203
Contact Person:	Aaron J. Sorensen, C.P.O. President
Telephone:	(615) 327-1100 (telephone) (615) 327-1141 (fax)
Preparation Date:	June 2001
Device Trade Name:	RHS Helmet
Common Name:	Cranial Orthosis
Classification Name:	Cranial Orthosis (see 21 C.F.R. § 882.5970) Product Code: MVA
Predicate Device:	Clarren Helmet -- 510(k) # 003035
Device Description:	The RHS Helmet is a cranial orthosis that applies passive pressure to prominent regions of an infant's cranium in order to improve cranial symmetry and/or shape in infants from 3 to 18 months of age with moderate to severe nonsynostotic positional plagiocephaly. It consists of a polypropylene helmet, three-eighths of an inch thick, that is vacuum formed over a plaster model of a baby's head to produce a helmet. A liner for the helmet is made of plastizote, one-fourth of an inch in thickness. Small holes are bored in the helmet for ventilation, and large holes for the child's ears.
Intended Use:	The Cranial Helmet is a cranial orthosis that applies passive pressure to prominent regions of an infant's cranium in order

	to improve cranial symmetry and/or shape in infants from 3 to 18 months of age with moderate to severe nonsynostotic positional plagiocephaly, including infants with plagiocephalic, brachycephalic, and scaphocephalic- shaped heads.
Performance Data:	Information was provided on the biocompatibility of the materials and the safety and effectiveness of helmet therapy.
CONCLUSIONS:	Based on the foregoing and other information in this application, RHS, Inc. believes that the Cranial Helmet is substantially equivalent to its claimed predicate under conditions of intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 1 9 2001

Restorative Health Services, Inc.
c/o Mr. David J. Bloch
Reed Smith
1301 K Street, N.W.
Suite 1100-East Tower
Washington, D.C. 20005

Re: K012007
Trade/Device Name: RHS Helmet
Regulation Number: 882.5970
Regulation Name: Cranial Orthosis
Regulatory Class: II
Product Code: MVA
Dated: June 27, 2001
Received: June 27, 2001

Dear Mr. Bloch:

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,

Susan Walker, MD

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

510(k) Number: K012007

Device Name: RHS Helmet

INDICATIONS FOR USE:

The RHS Helmet is a cranial orthosis that applies passive pressure to prominent regions of an infant's cranium in order to improve cranial symmetry and/or shape in infants from 3 to 18 months of age with moderate to severe nonsynostotic positional plagiocephaly, including infants with plagiocephalic, brachycephalic, and scaphocephalic- shaped heads.

* * *

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-the-Counter Use _____
(Per 21 C.F.R. 801.109)

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

510(k) Number K012007