K012830
PG 1 of 3

NOV 2 0 2001

510(k) Summary
Lerman & Son Cranial Orthosis Helmet
Lerman & Son

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

Lerman & Son
8710 Wilshire Blvd.
Beverly Hills, California 90211
Phone: (310) 659-2290
Facsimile: (310) 659-1601

Contact Persons: Max Lerman, President

Date: August 20, 2001

807.92(a)(2)

Trade Name: Lerman & Son Cranial Orthosis Helmet

Common Name: Cranial Helmet

Classification Name(s): Orthosis, Cranial

Classification Number: MVA

807.92(a)(3)

Predicate Device(s)

Orthomerica	STARband	K001167

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

510(k) Summary
Lerman & Son Cranial Orthosis Helmet
Lerman & Son

807.92(a)(5)

Intended Use(s)

The Lerman & Son Cranial Orthosis Helmet is intended to be used by or under the direction of a physician for treatment of abnormal head shape in infants from 3-18 months of age (positional/ deformational plagiocephaly).

Device Description

The Lerman & Son Cranial Orthosis Helmet is a custom made orthosis used to treat children between the ages of three and eighteen months for abnormal head shapes. Through the concavity formed during the design of this helmet, the skull is encouraged to grow in a more normal manner.

The Lerman & Son Cranial Orthosis Helmet is intended for use by or under the direction of a physician for treatment of abnormal infant head shape (positional/ deformational plagiocephaly).

The Lerman & Son Helmet is substantially equivalent to Orthomerica's STARband helmet cleared by FDA via K001167. A Substantial Equivalency table has been included within this submission.

Materials:	Helmet-Copolymer plastic; Padding-Closed cell foam polypropylene
Straps:	Velcro
Final shape:	Dependant upon infant head shape
Size:	Side to side – 4"-5-1/2" Front to back – 6"-7-1/2"
Weight:	8 – 12 ounces

510(k) Summary
Lerman & Son Cranial Orthosis Helmet
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Substantial Equivalence Comparison Table

	Orthomerica STARband K001167	Lerman & Son 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
Avg. Time to Effectiveness (patients age 3-7 mos.)	2 - 4 months	2 - 4 months
Contraindications for Use	Craniosynostosis/ Hydrocephalus	Craniosynostosis/ Hydrocephalus
Method of Manufacture	Custom from mold	Custom from mold by Certified Orthotist

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 2 0 2001

Mr. Max Lerman
President
Lerman & Son
8710 Wilshire Boulevard
Beverly Hills, California 90211

Re: K012830
Trade/Device Name: Lerman & Son Cranial Orthosis Helmet
Regulation Number: 882.5970
Regulation Name: Cranial Orthosis
Regulatory Class: II
Product Code: MVA
Dated: August 20, 2001
Received: August 23, 2001

Dear Mr. Lerman:

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.

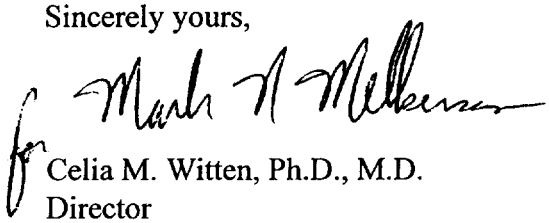
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 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

K012830

Indications for Use Statement

Applicant: Lerman & Son

510(k) Number (if known): _____ NOV 2 0 2001

Device Name: Lerman & Son Cranial Orthosis Helmet

Indications For Use:

The Lerman & Son Cranial Orthosis Helmet is intended to be used by or under the direction of a physician for treatment of abnormal head shape in infants from 3-18 months of age (positional/ deformational plagiocephaly).

(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)

Mark N Milhizer

for K012830

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

510(k) Number K012830