510(k) Summary of Safety and Effectiveness

APR 1 8 2014

In accordance with 21 CFR 807.87 (h) and 21 CRF 807.92, the 510(k) summary for the P-POD Plagiocephaly Orthosis Device is provided below.

Date	4/15/2014
Manufacturer/Distributor/Sponsor	Lorica Scientific LLC 750 Old Ludlow Ave. Cincinnati, OH 45220 Phone 440-315-7830 Fax 513-221-2905
510(k) Contact	Secure BioMed Evaluations Linda Braddon, Ph.D. 7828 Hickory Flat Highway Suite 120 Woodstock, GA 30188 770-837-2681 (direct) 855-MED-DEV1 (office) LGB@SecureBME.com
Trade Name	Plagiocephaly Orthosis Device
Common Name	Cranial Orthosis
Code Classification	**MVA** 21 CFR 882.5970 : Class II
Predicate Devices	K072566 Hanger Cranial Band™ K021918 Clarren Helmet

Device Description

The Lorica Scientific LLC P-POD Plagiocephaly Helmet is a Class II cranial orthosis intended for medical purposes to apply static or gentle pressure to prominent regions of an infant's cranium to improve cranial symmetry or shape. The device is intended to treat infants from four to eighteen months of age with moderate to severe non-synostotic positional plagiocephaly, including plagiocephalic-, brachycephalic-, scaphocephalic-shaped heads. The P-POD helmet is similar to the predicate devices in such that it is an orthosis designed for each patient from a cast of the infant's head. Each orthosis is composed on an outer shell with a layer of foam and a side strap for securing the orthosis. Additionally, the helmet has a top vent and side opening as typically seen with the predicates. Optimum fit and alignment is insured and monitored by the clinical practitioner.

The Lorica Scientific LLC P-POD Plagiocephaly Helmet differs from the predicate devices in that the device is made in the physician's office via a simplified casting process that can be performed in approximately 30 minutes. The predicate devices rely on a 2 to 4 week process of sending the child for a 3-D scan and then using casting and molding processes to create a customized helmet.

The P-POD standardized (2 sizes) helmet consists of a hard outer shell with an inflatable bladder lining the inside. Modeling putty is used to fill in the flattened portion of the infants head to form the desired

symmetrical shape and the helmet is placed on the infant. The physician then mixes a pre-measured solution in an easy-to-use, pre-measured pouch and pours the mixed solution into the bladder of the helmet through a specially designed filling port located at the top of the helmet. As the chemical solution cures, there is an exothermic foaming process from a liquid to solid foam which expands to fill the empty space in the bladder thus customizing the helmet to the shape making a negative copy of the infant's skull. Since the putty is used to fill in the undesired negative regions of the skull deformity, once the foam is completely cured and putty removed, the resulting helmet provides an ideal cast to help promote proper skull re-contouring. As with all other similar cranial orthosis devices, as the infant wears the helmet, the head grows into the shape formed by the foam, thereby correcting the deformity.

Intended Use

The P-POD Helmet is a cranial orthosis device intended for medical purposes to apply static or gentle pressure to prominent regions of an infant's cranium to improve cranial symmetry or shape. The device is intended to treat infants from four to eighteen months of age with moderate to severe non-synostotic positional plagiocephaly, including plagiocephalic-, brachycephalic-, scaphocephalic-shaped heads.

Technological Characteristics

The P-POD helmet is essentially the same as the predicate devices in such that it is an orthosis designed for each patient from a cast of the infant's head. Each orthosis is composed on an outer shell with a layer of foam and a strap for securing the orthosis. It has a top vent and side opening. Optimum fit and alignment is insured and monitored by the clinical practitioner.

The Lorica Scientific LLC P-POD Plagiocephaly Helmet differs from the predicate devices in that the device is made in the physician's office via a simplified casting process that can be performed in approximately 30 minutes.

Non-Clinical Performance Testing Conclusion

Non-clinical performance testing included biocompatibility with the following results:

Biocompatibility Tests	Results	Conclusions
ISO Cytotoxicity MEM Elution According to ISO 10993-5 Biological evaluation of medical devices: Part 5 Tests for In vitro Cytotoxicity	Cell culture treated with test sample exhibited no reactivity (Grade 0)	Non-toxic
Guinea Pig Maximization According to ISO 10993-10 Biological evaluation of medical devices: Part 10 Tests for irritation and delayed hypersensitivity	Albino guinea pigs treated with test sample did not elicit a sensitization response (Grade 0)	No sensitization reaction
Intracutaneous Irritation Reactivity According to ISO 10993-10 Biological evaluation of medical devices: Part 10 Tests for irritation and delayed hypersensitivity	Rabbits treated with test samples exhibited no irritation (Grade 0)	Non-irritating

Additional nonclinical testing included

- Evaluation of molding process accuracy
- Foam stiffness

Human factors studies were performed to ensure the following:

- Naïve users can be trained via a video and reading the IFU to produce a helmet and appropriately accept or reject a helmet based on defined criteria
- The infants in the intended treatment range of 4 to 18 months can tolerate the treatment

Substantial Equivalence Summary (Conclusion)

The Lorica Scientific LLC P-POD Helmet is very similar to cranial orthosis devices that are legally commercially available. A comparison between the P-POD Helmet and the predicate devices is shown in the following table.

Trait	P-POD Plagiocephaly Orthosis Device	Clarren	Hanger Cranial Band™	Evaluation of Differences
510(k) number	TBD	K021918	K072566	N/A
Product Classification	Class II 882.5970 MVA	Class II 882.5970 MVA	Class II 882.5970 MVA	Same
Use	Prescription Use Part 21 CFR 801 Subpart D	Prescription Use Part 21 CFR 801 Subpart D	Prescription Use Part 21 CFR 801 Subpart D	Same
Intended Population	4 to 18 months	3 to 18 months	3 to 18 months	No risk for change; P-POD more conservative
Intended Use	See section 12.2.1	See section 12.2.1	See section 12.2.1	Same
Product Design	Cranial orthosis made to individual's specifications	Cranial orthosis made to individual's specifications	Cranial orthosis made to individual's specifications	Same
Biocompatible Components	Yes	Yes	Yes	Same
Materials: Outer Shell	Polypropylene USP Class VI certified	Polypropylene customized to individual	Polypropylene or Polypropylene-Polyethylene Copolymer	Same or Equivalent
Materials: Bladder / Liner	Polyurethane liner filled with polyurethane foam	Polyurethane	Polyethylene foam	Same or Equivalent

Trait	P-POD Plagiocephaly Orthosis Device	Clarren	Hanger Cranial Band™	Evaluation of Differences
Helmet Production	Casting Manufactured by Physician in doctor's office on infant	Computer scan, Casting Manufactured by Orthotist	Computer scan, Casting Manufactured by Orthotist	No New Risk Differences in manufacturing helmets will not affect quality of final product. Human factors studies for P-POD helmet show physicians can make the helmet and determine adequacy of helmet for child.
Foam Stiffness	Durometer A 45 ± 4.61 Min: 39 Max: 54	Durometer A 64 ± 6.71 Min: 55 Max: 74	Durometer A 50 ± 9.36 Min: 39 Max: 65	Equivalent
Foam Thickness	0.1875 inches minimum	0.1875 inches	Not measured	Same
Daily Wearing Time	23 hours	23 hours	23 hours	Same
Daily Care	Cleaning daily with water and isopropyl alcohol	Cleaning daily with water and isopropyl alcohol	Cleaning daily with water and isopropyl alcohol	Same
Time from initial evaluation to application of treatment	Same day; Helmet is made onsite at the physician's office. As soon as a clinical need is determined, the treatment can start immediately	Typically 2 to 4 weeks delay from diagnosis to beginning of treatment	Typically 2 to 4 weeks delay from diagnosis to beginning of treatment	P-POD allows the immediate treatment of a diagnosed condition whereas predicates delay treatment for weeks
Adverse Effects	Device may cause skin irritations or breakdown	Device may cause skin irritations or breakdown	Device may cause skin irritations or breakdown	Same
Caregiver Instructions for Use	Wear and care guide provided to caregiver	Wear and care guide provided to caregiver	Wear and care guide provided to caregiver	Same
Discontinuance of Device Use	When infant outgrows the cranial helmet or orthosis is discontinued for any reason	When infant outgrows the cranial helmet or orthosis is discontinued for any reason	When infant outgrows the cranial helmet or orthosis is discontinued for any reason	Same

This submission demonstrates the equivalency in the indication for use, device classification, product code, environment of use, and the equivalency of the principles of operation. The Lorica Scientific LLC P-POD

Plagiocephaly Orthosis Device and the predicates underwent non-clinical evaluation which confirmed device equivalency. Additionally, the change in the helmet production process was validated in a two part human factors study which showed the P-POD device production process can be successfully produced by clinicians and is well tolerated by the intended infant population.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

April 18, 2014

P-POD
c/o Linda Braddon, Ph.D.
Secure BioMed Evaluation
7828 Hickory Flat Highway, Suite 120
Woodstock, Georgia 30188

Re: K133397
Trade/Device Name: P-POD Plagiocephaly Orthosis Device
Regulation Number: 21 CFR 882.5970
Regulation Name: Plagiocephaly Orthosis Device
Regulatory Class: Class II
Product Code: MVA
Dated: March 17, 2014
Received: March 20, 2014

Dear Dr. Braddon:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Felipe Aguel -S

for Carlos L. Peña, Ph.D, M.S.
Director
Division of Neurological and Physical
Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*
K133397

Device Name
P-POD Plagiocephaly Orthosis Device

Indications for Use *(Describe)*
The P-POD Plagiocephaly Orthosis Device is intended for medical purposes to apply static or gentle pressure to prominent regions of an infant's cranium to improve cranial symmetry or shape. The device is intended to treat infants from four to eighteen months of age with moderate to severe non-synostotic positional plagiocephaly, including plagiocephalic-, brachycephalic-, scaphocephalic-shaped heads.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Felipe Aguel -S Date: 2014.04.18 10:59:53 -04'00'

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