510(k) Summary of Safety and Effectiveness

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

<table>
<thead>
<tr>
<th>Date</th>
<th>4/15/2014</th>
</tr>
</thead>
</table>
| 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:

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

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.

<table>
<thead>
<tr>
<th>Trait</th>
<th>P-POD Plagiocephaly Orthosis Device</th>
<th>Claren</th>
<th>Hanger Cranial Band™</th>
<th>Evaluation of Differences</th>
</tr>
</thead>
<tbody>
<tr>
<td>510(k) number</td>
<td>TBD</td>
<td>K021918</td>
<td>K072566</td>
<td>N/A</td>
</tr>
<tr>
<td>Product Classification</td>
<td>Class II 882.5970 MVA</td>
<td>Class II 882.5970 MVA</td>
<td>Class II 882.5970 MVA</td>
<td>Same</td>
</tr>
<tr>
<td>Use</td>
<td>Prescription Use Part 21 CFR 801 Subpart D</td>
<td>Prescription Use Part 21 CFR 801 Subpart D</td>
<td>Prescription Use Part 21 CFR 801 Subpart D</td>
<td>Same</td>
</tr>
<tr>
<td>Intended Population</td>
<td>4 to 18 months</td>
<td>3 to 18 months</td>
<td>3 to 18 months</td>
<td>No risk for change; P-POD more conservative</td>
</tr>
<tr>
<td>Intended Use</td>
<td>See section 12.2.1</td>
<td>See section 12.2.1</td>
<td>See section 12.2.1</td>
<td>Same</td>
</tr>
<tr>
<td>Product Design</td>
<td>Cranial orthosis made to individual’s specifications</td>
<td>Cranial orthosis made to individual’s specifications</td>
<td>Cranial orthosis made to individual’s specifications</td>
<td>Same</td>
</tr>
<tr>
<td>Biocompatible Components</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Same</td>
</tr>
<tr>
<td>Materials: Outer Shell</td>
<td>Polypropylene USP Class VI certified</td>
<td>Polypropylene customized to individual</td>
<td>Polypropylene or Polyethylene- Polyethylene Copolymer</td>
<td>Same or Equivalent</td>
</tr>
<tr>
<td>Materials: Bladder / Liner</td>
<td>Polyurethane liner filled with polyurethane foam</td>
<td>Polyurethane</td>
<td>Polyethylene foam</td>
<td>Same or Equivalent</td>
</tr>
<tr>
<td>Trait</td>
<td>P-POD Plagiocephaly Orthosis Device</td>
<td>Clarren</td>
<td>Hanger Cranial Band™</td>
<td>Evaluation of Differences</td>
</tr>
<tr>
<td>-----------------------------</td>
<td>--------------------------------------</td>
<td>---------</td>
<td>----------------------</td>
<td>--------------------------</td>
</tr>
<tr>
<td>Helmet Production</td>
<td>Casting, Manufactured by Physician in doctor's office on infant</td>
<td>Computer scan, Casting, Manufactured by Orthotist</td>
<td>Computer scan, Casting, Manufactured by Orthotist</td>
<td>No New Risk</td>
</tr>
<tr>
<td>Foam Thickness</td>
<td>0.1875 inches minimum</td>
<td>0.1875 inches Not measured</td>
<td>Same</td>
<td></td>
</tr>
<tr>
<td>Daily Wearing Time</td>
<td>23 hours</td>
<td>23 hours</td>
<td>23 hours</td>
<td>Same</td>
</tr>
<tr>
<td>Daily Care</td>
<td>Cleaning daily with water and isopropyl alcohol</td>
<td>Cleaning daily with water and isopropyl alcohol</td>
<td>Cleaning daily with water and isopropyl alcohol</td>
<td>Same</td>
</tr>
<tr>
<td>Time from initial evaluation to application of treatment</td>
<td>Same day; Helmet is made onsite at the physician's office. As soon as a clinical need is determined, the treatment can start immediately</td>
<td>Typically 2 to 4 weeks delay from diagnosis to beginning of treatment</td>
<td>Typically 2 to 4 weeks delay from diagnosis to beginning of treatment</td>
<td>P-POD allows the immediate treatment of a diagnosed condition whereas predicates delay treatment for weeks</td>
</tr>
<tr>
<td>Adverse Effects</td>
<td>Device may cause skin irritations or breakdown</td>
<td>Device may cause skin irritations or breakdown</td>
<td>Device may cause skin irritations or breakdown</td>
<td>Same</td>
</tr>
<tr>
<td>Caregiver instructions for Use</td>
<td>Wear and care guide provided to caregiver</td>
<td>Wear and care guide provided to caregiver</td>
<td>Wear and care guide provided to caregiver</td>
<td>Same</td>
</tr>
<tr>
<td>Discontinuance of Device Use</td>
<td>When infant outgrows the cranial helmet or orthosis is discontinued for any reason</td>
<td>When infant outgrows the cranial helmet or orthosis is discontinued for any reason</td>
<td>When infant outgrows the cranial helmet or orthosis is discontinued for any reason</td>
<td>Same</td>
</tr>
</tbody>
</table>

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.
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" (21 CFR 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
Indications for Use

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)

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

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

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.
This section applies only to requirements of the Paperwork Reduction Act of 1995.

*DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.*

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services  
Food and Drug Administration  
Office of Chief Information Officer  
Paperwork Reduction Act (PRA) Staff  
PRAStaff@fda.hhs.gov

*An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number.*