June 7, 2021

HeadStart, Ltd.
% Dave McGurl
Director, Regulatory Affairs
MCRA, LLC
1050 K Street NW, Suite 1000
Washington, District of Columbia 20001

Re: K193383
Trade/Device Name: SnugKap
Regulation Number: 21 CFR 882.5970
Regulation Name: Cranial Orthosis
Regulatory Class: Class II
Product Code: MVA
Dated: May 7, 2021
Received: May 7, 2021

Dear Dave McGurl:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Adam D. Pierce, Ph.D.
Assistant Director
DHT5A: Division of Neurosurgical,
Neurointerventional
and Neurodiagnostic Devices
OHT5: Office of Neurological
and Physical Medicine Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K193383

Device Name
SnugKap

Indications for Use *(Describe)*
The SnugKap is intended for medical purposes for use on infants from 3 to 18 months of age, with moderate to severe nonsynostotic positional Plagiocephaly, including infants with plagiocephalic-, brachycephalic-, and scaphocephalic-shaped heads by applying mild pressure to prominent regions of the infant's cranium in order to improve cranial symmetry and/or shape. The device is also indicated for adjunctive use for infants from 3 to 18 months of age whose synostosis has been surgically corrected, but who still have moderate to severe cranial deformities including plagiocephalic-, brachycephalic- and 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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary
K193383

Device Trade Name: SnugKap

Manufacturer:
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Date Prepared: June 7, 2021

Classifications: 21 CFR 882.5970, Cranial Orthosis

Class: II

Product Codes: MVA

Primary Predicate: The subject devices are substantially equivalent to the following primary predicate device and reference devices.

Table 1: Primary Predicate Device

Manufacturer	Device Name	K Number
Primary Predicate		
Eastern Cranial Affiliates, LLC	KidCap	K180568
Reference Devices		
Lorica Scientific, LLC	P-POD	K133397
Orthomerica Products, Inc.	STARBand, STARlight, St. Louis Band	K180109
Fairview Orthopedic Laboratory	Molded Cranial Helmet	K012920

Indications for Use:
The SnugKap is intended for medical purposes for use on infants from 3 to 18 months of age, with moderate to severe nonsynostotic positional Plagiocephaly, including infants with plagiocephalic-, brachycephalic-, and scaphocephalic-shaped heads by applying mild pressure to prominent regions of the infant's cranium in order to improve cranial symmetry and/or shape. The device is also indicated for adjunctive use for infants from 3 to 18 months of age whose synostosis has been surgically corrected, but who still have moderate to severe cranial deformities including plagiocephalic-, brachycephalic- and scaphocephalic-shaped heads.

Device Description:
The SnugKap devices are cranial orthoses intended to be utilized on infant patients that suffer from head shape abnormalities. The SnugKap devices are additively manufactured from a 3D scan file of the patient's head. The scan file is digitally modified to address the anatomical/shape abnormalities in the skull. The SnugKap is then 3D printed and fabricated according to the case plan approved by the orthotist. The SnugKap is manufactured from a copolymer made of polylactic acid; additional parts are made of a variety of materials including thermoplastic polyurothane, polypropylene, and Plastazote® (white or pink) polymer foam.

Predicate Device:
The SnugKap is substantially equivalent to a previously cleared predicate devices and has the same indications for use and function; and similar design and materials. The primary predicate device is the KidCap (K180568). The reference devices are the P-POD, STARBand, and Molded Cranial Helmet (K133397, K180109, and K012920 respectively).

Performance Testing Summary:
Testing performed on the subject device includes worst case determination, strength testing (band), durability testing (open-close test), and pressure testing. Additional testing included biocompatibility, software validation and 3D printing validation testing. Each of these studies were designed to address risks and demonstrate substantially equivalent performance to predicate devices. Additional details on the testing is provided in the substantial equivalence table below.

Sterilization and Cleaning:
The SnugKap device is provided clean and non-sterile and is required to be cleaned prior to initial use and cleaned daily after each use. Shelf-life data is not needed to establish maintenance of device performance characteristics over the useful life period, because of the low likelihood of time-dependent material degradation.

Substantial Equivalence Summary:
Comparative information presented in the 510(k) supports the substantial equivalence of the SnugKap to the primary predicate devices. Comparisons were designed to show the indications, intended use, design, and performance are equivalent between the SnugKap and primary predicate devices. An evaluation table is provided below:

Attribute	Subject Device	Primary Predicate	Reference Devices			Comparison (Subject Device vs. Predicate Devices)
	SnugKap	KidCap	P-POD	STARBand, STARlight, St. Louis Band	Molded Cranial Helmet	
510(k) Number	K193383	K180568	K133397	K180109	K012920	**N/A**
Company	HeadStart Ltd.	Eastern Cranial Affiliates, LLC	Lorica Scientific, LLC	Orthomerica Products, Inc.	Fairview Orthopedic Laboratory	**N/A**
Regulation	21 CFR 882.5970	21 CFR 882.5970	21 CFR 882.5970	21 CFR 882.5970	21 CFR 882.5970	**Identical**
Classification	II	II	II	II	II	**Identical**
Product Code	MVA	MVA	MVA	MVA, OAN	MVA	**Identical**
Indications for Use	The SnugKap is intended for medical purposes for use on infants from 3 to 18 months of age, with moderate to severe nonsynostotic positional Plagiocephaly, including infants with plagiocephalic-, brachycephalic-, and scaphocephalic-shaped heads by applying mild pressure to prominent regions of the infant's cranium in order to improve cranial symmetry and/or shape. The device is also indicated for adjunctive use	The KidCap is a cranial orthosis used to treat abnormally shaped craniums in infants between the ages of three (3) months to eighteen (18) months of age. It is designed to address abnormal cranial configurations classified as nonsynostotic positional plagiocephaly and post-operative nonsynostotic plagiocephaly. It includes infants with plagiocephalic, brachycephalic and scaphocephalic patterned head shapes, and post-operative craniosynostosis	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.	The STARband, STARlight, and St. Louis Band are intended for medical purposes for use on infants from 3 to 18 months of age, with moderate-to-severe non-synostotic positional plagiocephaly, including infants with plagiocephalic-, brachycephalic- and scaphocephalic-shaped heads by applying mild pressure to prominent regions of the infant's cranium in order to improve cranial symmetry and/or shape. These devices are also indicated for adjunctive use for infants from 3 to 18 months of age whose synostosis has been surgically corrected, but who still have moderate-to-severe cranial deformities	The Molded Cranial Helmet is used to treat children 3-18 months of age for moderate to severe non-synostotic positional plagiocephaly, including infants with plagiocephalic-, brachycephalic- and scaphocephalic-shaped heads. The device is intended for medical purposes to apply pressure to prominent regions of an infant's cranium in order to improve cranial symmetry and/or shape. The device is for use by or on the order of a physician.	**Similar:** The subject device and predicated devices are cranial orthoses that improve symmetry and cranial shape by using the static equilibrium principle by applying pressure to prominent regions.

Attribute	Subject Device	Primary Predicate	Reference Devices			Comparison (Subject Device vs. Predicate Devices)
	SnugKap	KidCap	P-POD	STARBand, STARlight, St. Louis Band	Molded Cranial Helmet	
	for infants from 3 to 18 months of age whose synostosis has been surgically corrected, but who still have moderate to severe cranial deformities including plagiocephalic-, brachycephalic- and scaphocephalic-shaped heads.	management. The KidCap utilizes the principles of static equilibrium to influence the cranial plates while utilizing an anatomical kinetic chain to influence the bones comprising the orbits, cheek structure, and lower mandible. The orthosis is designed to intimately contact the prominences of the expanding cranium but will not initiate a force upon the cranium.		including plagiocephalic, brachycephalic- and scaphocephalic-shaped heads.		
Use	Prescription Use	Prescription Use	Prescription Use	Prescription Use	Prescription Use	**Identical**
Population	3 to 18 months	3 to 18 months	4 to 18 months	3 to 18 months	3 to 18 months	**Similar:** The P-POD predicate device is limited to a lower age boundary of 4 months instead of 3 months. The rest of the predicate device share the exact same age range of infants.
Anatomical Site	Cranium	Cranium	Cranium	Cranium	Cranium	**Identical**

Attribute	Subject Device	Primary Predicate	Reference Devices			Comparison (Subject Device vs. Predicate Devices)
	SnugKap	**KidCap**	**P-POD**	**STARBand, STARlight, St. Louis Band**	**Molded Cranial Helmet**	
Product Design	Cranial orthosis made to individual's specifications	Bivalved 2-piece polymer shell with padded interface	Cranial orthosis made to individual's specifications	Cranial orthosis made to individual's specifications	Cranial orthosis made to individual's specifications	**Identical**
Patient Contact Duration (Wearing Time)	Day 1: 8 hrs./day (2x4 hrs.) Day 2: 8 hrs./day (1x8 hrs.) Day 3: 12 hrs./day (1x12 hrs.) Day 4: 16 hrs./day (1x16 hrs.) Subsequent days: 23 hrs./day	N/A	23 hours/day	23 hours/day	N/A	**Similar:** The SnugKap device is meant to be worn continuously for 23 hours per day after an ease-in period of three days that follows a recommended progressive use schedule. The P-POD and STARBand equivalent devices, are also meant to be utilized for 23 continuous hours per day. The recommended ease-in period will allow the baby to familiarize with the SnugKap and increase comfort.
Materials	• Polylactic acid • Plastazote (closed-cell cross-linked polypropylene foam) white or pink • Thermoplastic Polyurothane • Polypropylene	• Durr Plex™ • Hypoallergenic Suspension Padding	• Polypropylene (USP Class VI certified) • Polyurethane foam	• Copolymer plastic • Pelite polyethylene foam • Aliplast foam • Clear surlyn • Clear co-polyester • Velcro strap • Chafe buckle	• Plastazote (closed-cell cross-linked polypropylene foam) • Polypropylene outer shell	**Similar** All devices' shells/bands are manufactured from copolymers. All devices' straps or ancillary parts are manufactured from a variety of polypropylene and

Attribute	Subject Device	Primary Predicate	Reference Devices			Comparison (Subject Device vs. Predicate Devices)
	SnugKap	KidCap	P-POD	STARBand, STARlight, St. Louis Band	Molded Cranial Helmet	
						polyethylene foams. All materials have been previously used for medical applications and are not expected to cause any adverse events when in contact with skin and hair.
Biocompatibility	• Sensitization • Cytotoxicity • Irritation	• Materials are not reported to cause skin irritation or any toxic harms	• MEM Elution • Guinea Pig Maximization • Intracutaneous Reactivity	• Cytotoxicity –Agar Diffusion • Closed Patch Sensitization • Primary Dermal Irritation	• Biocompatibility Assessment	**Equivalent**
Manufacturing	A 3D image is used to produce a 3D printed band	A 3D image is used to produce a positive mold from which the band is manufactured	A cast is made by the physician. The casting tools include a hard shell with an inflatable bladder lining, modeling putty, and a pre-mixed solution that cures by exothermic foaming process	A 3D image is used to produce a positive mold from which the band is manufactured with plaster or carved out of a polyurethane foam blank	A plaster mold of the users head is made by the physician. Trimming and sizing are prepared by an orthotist and technicians from the mold.	**Different** The KidCap and STARBand predicate devices as well as the subject device utilize 3D images to manufacture the orthosis in an industrial manner. The predicate P-POD utilizes a manual process in which the orthosis can be manufactured in the physician's office. The manufacturing process of the orthosis is different between the subject device and

Attribute	Subject Device	Primary Predicate	Reference Devices			Comparison (Subject Device vs. Predicate Devices)
	SnugKap	KidCap	P-POD	STARBand, STARlight, St. Louis Band	Molded Cranial Helmet	
						predicate devices, in which the subject device is additively manufactured instead of
Performance	• Software Validation, Process Validation • 3D Printing Validation • Durability Testing	• Software Validation, Process Validation • Dimensional Equivalency Comparison for mold acquisition method	• N/A	• Cranial Shape Capture Accuracy Study	• Literature articles for safety and effectiveness	**Similar:** Performance testing ensures that the subject devices perform as intended.
Cleaning	Daily with isopropyl alcohol	Daily with isopropyl alcohol	Daily with isopropyl alcohol	Daily with isopropyl alcohol	Daily with isopropyl alcohol	**Identical**
Discontinuation of Device Use	When infant outgrows the cranial orthosis. Approximately 12-18 weeks	N/A	When infant outgrows the cranial orthosis	N/A	N/A	**Similar:** Even though labeling between devices has different wording, the estimated lifespan of the subject and equivalent devices is when the patient outgrows the orthosis which has been estimated to be approximately 4 months.

Conclusion:

The information and performance data demonstrate that the device is substantial equivalent and performs as well as the primary predicate device. The subject SnugKap is substantially equivalent to the predicate devices (K133397, K180568, K012920 and K180109), with respect to indications, design, materials, function, and performance.