October 16, 2018

Eastern Cranial Affiliates, LLC
Joseph Terpenning
Director Of Orthotics
10523 Main Street
Fairfax, Virginia 22030

Re: K180568
Trade/Device Name: KidCap
Regulation Number: 21 CFR 882.5970
Regulation Name: Cranial Orthosis
Regulatory Class: Class II
Product Code: MVA
Dated: October 17, 2016
Received: March 5, 2018

Dear Joseph Terpenning:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Matthew C. Krueger -S

for Carlos L. Peña, PhD, MS
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K180568

Device Name

KidCap™

Indications for Use *(Describe)*

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 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. The KidCap™ is only available if prescribed by a physician.

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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1.5. 510(k) Summary

510(k) Number:

Date Prepared: October 17, 2016

Submitter Information

Submitter: Eastern Cranial Affiliates
10523 Main St.
Fairfax, Virginia 22030
Registration Number: 3005021665
Owner/Operator Number: 9049723

Contact Person: Joseph Terpenning
Tel: (703) 807-5899
Fax: (703) 807-1183
jterpenning@infinitetech.org

Device Information

Trade Name	KidCap™
Common/Usual Name	Cranial Orthosis
Classification Name	Cranial Orthosis
Regulation/Product Code	882.5970/MVA
Regulatory Classification	Class II
Device Panel	Neurology

Predicate Device(s): KidCap™ is substantially equivalent to the previously-cleared, K020448.

510(k) Number	Device Name/Submitter
K020448	Static Cranioplasty Orthosis/Eastern Cranial Affiliates

Device Description

The KidCap™ is a cranial orthosis used to treat abnormally shaped craniums in infants three (3) to eighteen (18) months of age. The orthosis contains the protruding aspects of the cranium in a static equilibrium while guiding the growth of the flattened areas of the skull into the created spaces.

The orthosis is custom designed for each patient by obtaining a three-dimensional scan of the patient cranium using the Omega Scanner. The scan of the cranium is translated into a digital image of the shape in the Computer Aided Design (CAD) software. From the digital image a positive model is generated by Ohio Willow Wood using a CAD carver. The positive model is then used to manufacture the KidCap™. The orthosis is composed of a rigid polymer shell, Durr Plex™ with biocompatible foam padding. The orthosis is held together with a polyethylene hinge, and two lateral guides composed of Polypropylene. The external pieces are adhered to the orthosis with polymer rivets that are countersunk into the interior for a smooth, unobtrusive transition with the orthosis.

The anterior and posterior sections of the orthosis are held secure with a 3/4" Velcro™ strap that encircles the posterior hemisphere of the orthosis. The orthosis has ventilation apertures to promote convectionary cooling as the patient perspires

Intended Use/Indications for 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 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. The KidCap™ is only available if prescribed by a physician.

Basis for Substantial Equivalence Table

Characteristic of Equivalence	**Predicate Device: Static Cranioplasty Orthosis K020448**	**Equivalent Device: KidCap™**
Indications for use	Reshaping of an infant's head with nonsynostotic plagiocephalic, brachycephalic and scaphocephalic head shapes	Reshaping of an infant's head with nonsynostotic plagiocephalic, brachycephalic and scaphocephalic head shapes
Target Population	Infants 3-18 months of age	Infants 3-18 months of age
Design	Bivalved 2-pience polymer shell with padded interface	Bivalved 2-pience polymer shell with padded interface
Biocompatibility	Materials are not reported to cause skin irritation or any toxic harms	Materials are not reported to cause skin irritation or any toxic harms
Mechanical safety	Device is non-mechanical, containing no active parts. Device is inherently safe, but not a protective device.	Device is non-mechanical, containing no active parts. Device is inherently safe, but not a protective device.
Chemical safety	Orthosis is non-reactive with patients skin	Orthosis is non-reactive with patients skin
Anatomical sites	Cranium, frontal bone, occiput, temporozygomatic arch, openings for eye fissures, and auditory canals	Cranium, frontal bone, occiput, temporozygomatic arch, openings for eye fissures, and auditory canals
Energy used/delivered	N/A	N/A
Location of use	Home and through daily activities	Home and through daily activities
Electrical safety	Polymer is nonconductive	Polymer is nonconductive
Fabrication of the Orthosis	A Negative impression filled with liquid plaster forms the positive mold	3-dimensional scan of the cranium is obtained using the OMEGA Tracer Software and Scanner which is then used to create the positive mold
Sterility	Device is not required to be sterilized for use	Device is not required to be sterilized for use
Performance	Effectiveness has been proven statistically significant by Paired T-tests of clinical data	Software Validation, Process Validation, and Dimensional Equivalency Comparison for mold acquisition method
Materials Used	Durr Plex™, Hypoallergenic Suspension Padding	Durr Plex™, Hypoallergenic Suspension Padding

Summary of Testing

Non-Clinical testing being submitted in this 510(k) includes software validation documents, process validation documents and a summary report detailing the dimensional equivalency comparison between the mold acquisition methods. The software validation documents executed for the Omega Tracer Software and Class I Omega Scanner Laser Device include the risk assessment, system requirement specification, installation qualification, operational qualification, and performance qualification. Additionally being submitted is the summary of the process validation which employed the use of the Omega Tracer Software and Scanner used in the manufacturing of the KidCap™ and the Dimensional Equivalency Comparison Report. The comparison report in combination with the protocol execution and testing supports a determination of substantial equivalence by showing that the use of the Omega Tracer Software and Scanner for the purpose of mold acquisition, patient assessment, and measurement analysis when fabricating a cranial molding helmet is equivalent to the previous method of obtaining a plaster impression of the patient's skull.

Conclusions

The KidCap™ has identical indications for use as the predicate device, the Static Cranioplasty Orthosis, and identical technological characteristics. Minor feature differences do not raise any new questions regarding safety or effectiveness of the device. The KidCap™ performs as intended, and presents no unacceptable risks to the intended patient population or end user. The KidCap™ is substantially equivalent to the predicate device.