



September 28, 2021

PediaMetrix, Inc.
Joshua Levin
Regulatory Advisor
155 Gibbs Street, Suite 537
Rockville, Maryland 20850

Re: K212045
Trade/Device Name: SoftSpot™
Regulation Number: 21 CFR 878.4800
Regulation Name: Manual surgical instrument for general use
Regulatory Class: Class I
Product Code: QQQ
Dated: June 26, 2021
Received: June 30, 2021

Dear Joshua Levin:

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,

Jay R. Gupta -S

Jay Gupta
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

Indications for Use

510(k) Number (if known)

K212045

Device Name

SoftSpot™

Indications for Use (Describe)

SoftSpot™ is intended to be used for cranial measurement for infants from 1 month up to 2 years of age in conjunction with other clinical methods.

SoftSpot™ is not intended to be used as a tool for preparing a helmet.

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.

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
PRASStaff@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."

510(k) Summary

A. Basic Information:

The submitter's name: PediaMetrix Inc

Address: 155 Gibbs St, Suite 537, Rockville, MD 20850

Telephone number: 240-670-0171

Contact: Joshua Levin, PhD.

The date the summary was prepared: 09-26-2021

B. 510(k) Number:

K212045

C. Device Proprietary and Established Names:

SoftSpot™

D. Regulatory Information:

1. Classification Name: Manual surgical instrument for general use (21 CFR 878.4800)
2. Classification: Class I
3. Product code: QQQ, Cranial measurement software
4. Panel: Neurology

E. Indications for Use:

1. Indications for use:
SoftSpot™ is intended to be used for cranial measurement for infants from 1 month up to 2 years of age in conjunction with other clinical methods.
SoftSpot™ is not intended to be used as a tool for preparing a helmet
2. Special conditions for use statement(s):
For prescription use only.

F. Predicate Device:

1. Predicate device name(s): Holtain-Kahn Caliper
2. Predicate 510(k) number(s): 510(k) Exempt
3. Product Code: FTY (Tape, Measuring, Rulers and Calipers)
4. Classification Regulation: 21 CFR 878.4800

G. Device Description:

SoftSpot™ is a software that runs on a smartphone, tablet, PC, etc. and uses top view pictures of infant's head to measure cranial index (CI) and cranial vault asymmetry index (CVAI) similar to a mechanical caliper used by physicians which is also known as craniometer.

After the photo is taken, the head contour is identified and then, based on the current standards of measuring infants' head shape, characterizing parameters including the ratio of width over length (known as Cranial Index or CI) and the ratio of difference in diagonals over the larger one (known as Cephalic Vault Asymmetry Index or CVAI) are calculated (see Test Principle below).

The SoftSpot platform allows different users to upload or capture top view videos and photos of the infant's head. The user can be a physician/nurse (during well visits) or parents/guardians (between the visits). Once data are collected, they are sent to PediaMetrix Amazon Web Services (AWS) cloud. At PediaMetrix, the data analyst will use a windows-based software to download and analyze the data. The analysis includes conversion of the video into photos, standardization of the images (3x4, all nose up), selection of 5 good images, segmentation of the head contour and nose tip. Then, the software will calculate CI and CVAI. Finally, a pdf report is generated with the results and sample top view photos and sent to the physician's account. Parents will also be notified when the results are ready. Then, the parent visits the physician (either in person or online) to discuss the results and next steps.

H. Measurand:

Cranial Index (CI) and Cephalic Vault Asymmetry Index (CVAI)

I. Measurement Principle:

The SoftSpot™ app calculates characterizing parameters including the ratio of width over length (known as Cranial Index or CI) and the ratio of difference in diagonals over the larger one (known as Cephalic Vault Asymmetry Index or CVAI) are calculated.

$$CI = \left(\frac{AP}{SD} \right) \times 100,$$

$$CVAI = \frac{AA - BB}{\max(AA, BB)} \times 100$$

- AP is defined on the head contour by the line that goes through the nose tip and center of the head contour.
- SD is defined by the line perpendicular at the midpoint of AP and intersecting the head contour.
- AA and BB are defined by the intersection of the head contour and the lines that go through the center of the head contour at +/-40 degrees relative to AP.

J. Comparison of Technological Characteristics with the Predicate Device:

Predicate Comparison - Similarities		
Item	Device	Predicate
	SoftSpot	Holtain-Kahn Caliper
Regulation	21 CFR 878.4800	21 CFR 878.4800
Product Code	TBD	FTY
Classification	Class I	Class I
Intended Use/Indications for Use	Used for cranial measurements in conjunction with other clinical methods.	Same as SoftSpot
Analytes measured	Cranial measurements	Same as SoftSpot

Predicate Comparison - Differences		
Item	Device	Predicate
	SoftSpot	Holtain-Kahn Caliper
Intended Use Population	Infants from 1 month to 2 years of age	Not specified
Measurement method	Software that uses pictures of the head to provide cranial measurements	Physical measurement of cranial parameters
Prescription/OTC	For prescription use; images may be collected by clinicians or parents/guardians	Not specified

K. Performance Data:1. Clinical Studies:*a. Prospective*

For the prospective evaluation of our measurement tool, PediaMetrix compared measurements taken with the SoftSpotTM app to the measurements taken by clinicians using a standard caliper similar to the predicate device. A comparative study was performed using 25 infants (age range 3 to 12 months). Data were collected by a physical therapist in a plagiocephaly clinic at the University of Pittsburgh Children Hospital from their typical patient population. The Spearman correlation coefficient was 0.96 and 0.94 for CI and CVAI, respectively. The mean absolute error (MAE) and standard deviation (STD) were 1.48 ± 0.92 and 1.44 ± 0.85 units for CI and CVAI, respectively.

b. Retrospective

We also compared SoftSpot measurements of 2D rendered images (from 3D head scans) with direct measurements from 3D scans of the head from patients with cranial deformities in a retrospective study using 100 infants' head measurements along with their 3D scans (in .stl format). Data were collected from patients aged 3-20 months with deformational plagiocephaly and brachycephaly (DPB) in a helmet clinic at Singapore. The Spearman correlation coefficient

was 0.93 and 0.94 for CI and CVAI, respectively. The mean absolute error (MAE) and standard deviation (STD) were 2.17 ± 1.53 and 1.62 ± 1.26 units for CI and CVAI, respectively.

L. Conclusions:

The proposed clinical studies demonstrated that the device can function as intended for the intended population (infants 1 months to 2 years of age) and that it can be used to measure CI and CVAI with accuracy comparable to the predicate device. This supports that the device is substantially equivalent to the predicate device.