July 18, 2019

Calcula Technologies, Inc
℅ Allison Komiyama
Principal Consultant
AcKnowledge Regulatory Strategies, LLC
2251 San Diego Avenue, Suite B-257
San Diego, CA 92110

Re: K190492
Trade/Device Name: Peralta Stone Removal Catheter
Regulation Number: 21 CFR 876.4680
Regulation Name: Ureteral Stone Dislodger
Regulatory Class: Class II
Product Code: FFL, EZN
Dated: June 7, 2019
Received: June 10, 2019

Dear Allison Komiyama:

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,

Glenn B. Bell, Ph.D.
Assistant Division Director
DHT3B: Division of Reproductive,
Gynecology and Urology Devices
OHT3: Office of Gastrorenal, ObGyn,
General Hospital and Urology 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K190492

Device Name
Peralta Stone Removal Catheter

Indications for Use *(Describe)*
The Peralta Stone Removal Catheter is intended to be used endoscopically to grasp, manipulate, and remove calculi from the urinary tract, and/or for ureteral dilation.

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.

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510(k) Summary

510(k) Summary
K190492

DATE PREPARED
July 18, 2019

MANUFACTURER AND 510(k) OWNER
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DEVICE INFORMATION

Proprietary Name/Trade Name:	Peralta Stone Removal Catheter
Common Name:	Dislodger, Stone, Basket, Ureteral, Metal
Regulation Description:	Ureteral stone dislodger
Regulation Number:	21 CFR 876.4680
Regulatory Class:	Class II
Product Code:	FFL, EZN
Premarket Review:	OPEQ/OHT3/DTH3B
Review Panel:	Gastroenterology/Urology

PREDICATE DEVICE IDENTIFICATION
The Peralta Stone Removal Catheter is substantially equivalent to the following predicates:

510(k) Number	*Predicate Device Name / Manufacturer*	*Primary Predicate*
K831875	Balloon Dilation Helical Stone Extractor / VPI	✓
K941853	Passport / Boston Scientific Corp	
510(k) Exempt	Zero Tip Nitinol Stone Retrieval Basket / Boston Scientific Corp.	*Reference Device*

The predicate devices have not been subject to a design related recall.

510(k) Summary

DEVICE DESCRIPTION

The Peralta Stone Removal Catheter (Peralta) is a 3 French (1 mm) catheter designed for removal of ureteral stones and fragments that are 5 mm or less in diameter in the urinary tract and ureteral dilation. The catheter uses a wire basket to encapsulate the stone, and a non-compliant balloon which can be inverted around the basket to cover the sharp edges of the stone during removal. The balloon can also be used for dilation of the urinary tract.

INDICATIONS FOR USE

The Peralta Stone Removal Catheter is intended to be used endoscopically to grasp, manipulate, and remove calculi from the urinary tract, and/or for ureteral dilation.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

Calcula believes that the Peralta Stone Removal Catheter is substantially equivalent to the predicate devices based on the information summarized here:

The subject device has a similar intended use and a similar design as the predicate device cleared in K831875, and similar dimensions and materials as the device cleared in K941853. The main differences between the primary predicate and subject devices are (1) the device cleared in K831875 features a helical basket made of four stainless steel wires and the subject device features a basket made of four nitinol wires and (2) the balloon of the subject device is able to invert around the captured stone and cover the sharp edges of the stone during removal. The technological characteristics of the subject device are similar in design, dimensions and materials, to the 510(k) exempt Zero Tip Nitinol Stone Retrieval Basket device marketed by Boston Scientific (reference device). The subject device has undergone testing to ensure that the device is substantially equivalent to the predicate and reference devices.

SUMMARY OF NON-CLINICAL TESTING

The Peralta Stone Removal Catheter conforms to the performance specifications outlined in FDA guidance document *Checklist for Mechanical Lithotripters and Stone Dislodgers used in Gastroenterology and Urology (Issued November 01, 1994)*

The following tests were performed to demonstrate safety based on current industry standards:

Biocompatibility: The subject device was subjected to biocompatibility testing in compliance to ISO 10993-5 *Biological evaluation of medical devices -- Part 5: Tests for In Vitro cytotoxicity* and ISO 10993-10 *Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization*

510(k) Summary

Performance: The performance testing of the subject device included dimensional verification, functional and performance testing, usability testing, and mechanical testing. *Ex vivo* testing in porcine ureters was performed to simulate real world use of the device.

Animal Testing: *In vivo* testing on four ureters in a porcine model that incorporated preplaced urinary stones (3 mm and 4.3 mm in size) was performed to simulate real world use of the device when compared to a currently marketed device.

The results of these tests indicate that the Peralta Stone Removal Catheter is substantially equivalent to the predicate devices.

SUMMARY OF CLINICAL TESTING

No clinical data were provided in order to demonstrate substantial equivalence.

CONCLUSION

Non-clinical testing (including biocompatibility, dimensional verification, functional and performance testing, usability and human factors testing, and mechanical testing) has been performed to demonstrate that any differences in technological characteristics do not raise new issues of safety or effectiveness. The similar indications for use, technological characteristics, and performance characteristics for the proposed Peralta Stone Removal Catheter are assessed to be substantially equivalent to the predicate devices and the reference device.