DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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September 19, 2017

THS International, Inc. dba Accordion Medical
David Quigley
President
9465 Counselors Row, Suite 200
Indianapolis, Indiana 46240

Re: K172299
Trade/Device Name: Accordion Piccolo Stone Management Device
Regulation Number: 21 CFR 876.4680
Regulation Name: Ureteral Stone Dislodger
Regulatory Class: Class II
Product Code: FFL
Dated: September 5, 2017
Received: September 11, 2017

Dear David Quigley:

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 Industry and Consumer Education (DICE) 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 (DICE) 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,

Charles Viviano -S

For Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological 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)*
K172299

Device Name
Accordion Piccolo Stone Management Device

Indications for Use *(Describe)*
The Accordion Piccolo Stone Management Device is intended to be used endoscopically to entrap and remove calculi and other foreign objects from the urinary tract and to guide instrumentation within the ureteral tract.

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

THS International, Inc. dba Accordion Medical's
Accordion Piccolo Stone Management Device

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

THS International, Inc. dba Accordion Medical
9465 Counselors Row Suite 200
Indianapolis, IN 46240

Phone: (317) 759-2869
Facsimile: (317) 688-8373
Contact Person: David Quigley
Date Prepared: June 30, 2017

Device Information

Proprietary Name:	Accordion Piccolo Stone Management Device (PA 1205-27-10)
Classification Name:	Ureteral Stone Dislodger
Product Code:	FFL
Device Class:	2

Predicate Devices/ Substantial Equivalence

Accordion Stone Management Device (PA 1205-06-10) (K052048)
Accordion CoAx Stone Control Device (PA 1305-01-10, PA 1305-01-15) (K082803)

Intended Use/Indications for Use

The Accordion Piccolo Stone Management Device is intended to be used endoscopically to entrap and remove calculi and other foreign objects from the urinary tract and to guide instrumentation within the ureteral tract.

Rational for Special 510k

Accordion Stone Management Device vs Accordion Piccolo	Effect on Intended Use	Alters the fundamental scientific technology of the device
Length of device: From 150cm to 94cm	No Change to Intended Use	No change to fundamental scientific technology of the device: Device still spans the ureteral length and is longer than average flexible and semi-rigid scopes **This length falls within already approved length parameters stated in the Accordion Stone Management Device 510k submission (K050428)**
Diameter of shaft: From 0.035" OD to 0.032"OD	No Change to Intended Use	No change to fundamental scientific technology of the device: still delivered with a cystoscope and can be used to pass other instrumentation **This diameter falls within already approved diameter parameters stated in the Accordion Stone Management Device 510k submission (K050428)**
Material of Shaft: From Pebax to Polyimide	No Change to Intended Use	No change to fundamental scientific technology of the device: Still biocompatible material: same material used in the CoAx Stone Control Device (K082803 on Nov. 13, 2008) with same Intended Use
Material of Core Wire: From Stainless steel to Nitinol	No Change to Intended Use	No change to fundamental scientific technology of the device: Same nitinol used in wires for Accordion occlusion film.

Device Description

The Accordion Piccolo's film membrane is attached to a two-part (inner and outer shaft) guidewire and deploys within the lumen of the ureter. The device can be advanced via the working channel of a cystoscope, and advanced under direct vision or fluoroscopy until the tip is proximal to the kidney stone or foreign object. To contain the stone during lithotripsy or entrap a foreign object, the movable core of the guidewire component is advanced by pulling on the handle, which causes the film membrane to deploy within the lumen of the ureter and prevent proximal movement of the stone or object during the surgical procedures.

The physician may maintain the film membrane in the deployed position and "sweep" the stone fragments down the ureter and into the bladder or use the deployed film as a "backboard" to prevent migration of the stone fragments into the kidney as he/she removes the fragments with a basket or other device.

Technological Characteristics

The Accordion Piccolo is fundamentally a shorter version of the Accordion Stone Management device (K052048). Its core wire, or inner shaft, uses Nitinol rather than stainless steel. The nitinol allows a more flexible tip which some Doctors prefer. Testing of the core wire was conducted to ensure that while the tip is more flexible, the device still performs the same functions. The Accordion Piccolo core wire is the same nitinol found in the occlusion film.

The braided shaft, or outer shaft, is the only material difference between the Accordion Piccolo and the Accordion Stone Management Device. The braided shaft of the Accordion Piccolo has the same polyimide material used in manufacturing of the braided shaft of the CoAx Stone Control Device (K082803). The change in materials allowed us a smaller diameter, preferred by doctors, without changing the functionality of the device, allowing the same structure but with a smaller diameter.

The occlusion film, handle, introducer, and all packaging components are the same as the Accordion Stone Management Device. Testing was conducted to ensure that the change diameter would not impact the functionality of the current Accordion Stone Control handle. The film, introducer and packaging are unchanged by the length or diameter changes.

Performance Data

50-0111-01 – Accordion Piccolo Benchtop Report (Full Device)

– Torque Handle grip test (Core wire and handle compatibility)

– Benchtop Test – Accordion Niti Floppiness test (Core wire testing)

– Benchtop test – Accordion Niti poke strength test (Core wire testing)

Conclusion

The Accordion Piccolo device testing demonstrates that the device is as safe, as effective, and performs as well as the Accordion Stone Management Device.

Previous Submissions for this device

N/A