K120468

JUL 6 2012

5. 510(k) Summary

Cook Incorporated
NCircle Nitinol Tipless Stone Extractor, NGage Nitinol Stone Extractor
510(k) Summary
21 CFR 807.92

1. Submitter Information

Applicant:	Cook Incorporated
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Contact:	Susanne Galin, RAC
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Contact Phone Number:	(812) 339-2235 x2296
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2. Device Information

Trade Name:	NCircle Nitinol Tipless Stone Extractor NGage Nitinol Stone Extractor
Common Name:	Endoscope and accessories
Classification:	Class II
Regulation:	21 CFR § 876. 1500 Endoscope and accessories
Product Code:	GCJ (Laparoscope, general and plastic surgery)

3. Predicate Devices

KSEA Sialoendoscopes and Accessories (Karl Storz Endoscopy – America, Inc., K012527)
NCircle Tipless Stone Extractor (Cook Medical, Class II 510(k) exempt under ProCode FFL)
NGage Nitinol Stone Extractor (Cook Medical, Class II 510(k) exempt under ProCode FFL)

4. Comparison to Predicates:

The technological characteristics of the NCircle Tipless Stone Extractor and the NGage Nitinol Stone Extractors in both their proposed and predicate form are identical in design, materials, and processing.

The intended use of the proposed devices are substantially equivalent in basic design and intended use to the KSEA Sialoendoscopy accessory stone basket manufactured by Karl Storz Endoscopy – America, Inc.

No new technological aspects are being introduced with the proposed devces.

5. Device Description

The NCircle Nitinol Tipless Stone Extractor and NGage Nitinol Stone Extractor are sterile, single use baskets which are used to manipulate, entrap, and extract calculi and other foreign bodies in the salivary ducts and to minimize migration during intracorporeal lithotripsy and/or other interventional procedures. The NCircle or NGage will be inserted into a salivary duct under direct visualization through a sialendoscope or introducer sheath to reach the calculi or other foreign body. The device can then snare the object and withdraw it from the body or help to maintain its position during lithotripsy prior to removal. The NCircle and NGage devices are intended for short-term use.

6. Intended Use

The NCircle Nitinol Tipless Stone Extractor is intended for manipulation, entrapment, and extraction of calculi and other foreign bodies in the salivary ducts and to minimize migration during intracorporeal lithotripsy and/or other lithotripsy procedures.

The NGage Nitinol Stone Extractor is intended for manipulation, entrapment, and extraction of calculi and other foreign bodies in the salivary ducts and to minimize migration during intracorporeal lithotripsy and/or other lithotripsy procedures.

7. Technological Characteristics

The NCircle Nitinol Tipless Stone Extractor consists of a 15 cm long, 1.5 Fr diameter sheath, inside which is a nitinol basket that can be exposed at the distal end. The nitinol wire forms a basket with 4 struts, crossing at the distal end, which constitutes the "tipless" design. The proximal end consists of a handle with a lever which operates both the exposure (opening) of the basket and the retraction (closure) of the basket. When fully in the open position, the basket is 1 cm in diameter.

The NGage Nitinol Stone Extractor consists of a 115 cm length, 1.7 Fr diameter sheath. Exposed at the distal end of the sheath is a nitinol basket with three struts. The basket is open at the distal end. The proximal end consists of a handle with a lever which operates the opening and closing of the basket (the basket does not retract into the sheath as does the NCircle). When fully in the open position, the basket is 0.8 cm in diameter.

To demonstrate reliable design and performance of the NCircle Nitinol Tipless Stone Extractor and the NGage Nitinol Stone Extractor, the following verification testing and information was presented:

- Tensile testing (basket wires)
- Tensile testing (sheath to handle)
- Biocompatibility testing
- Tensile testing (basket assembly to handle)
- Mechanical integrity testing
- Sterilization testing

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Cook Medical
% Ms. Susanne Galin, RAC
Regulatory Affairs Specialist
750 Daniels Way
Bloomington, IN 47402-0489

JUL 6 2012

Re: K120468
Trade/Device Name: NCircle Nitinol Tipless Stone Extractor and NGage Nitinol Stone Extractor
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: GCJ
Dated: June 20, 2012
Received: June 21, 2012

Dear Ms. Galin:

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

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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 yours,

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological and
Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K120468

4. Indications for Use Statement

510(k) Number (if known): K120468

Device Name: NCircle Nitinol Tipless Stone Extractor, NGage Nitinol Stone Extractor

Indications for Use:

The NCircle Nitinol Tipless Stone Extractor is intended for the manipulation, entrapment, and extraction of calculi and other foreign bodies in the salivary ducts, and to minimize migration during intracorporeal lithotripsy and/or other interventional procedures.

The NGage Nitinol Stone Extractor is intended for the manipulation, entrapment, and extraction of calculi and other foreign bodies in the salivary ducts, and to minimize migration during intracorporeal lithotripsy and/or other interventional procedures.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear, Nose and Throat Devices

510(k) Number K120468