DEC 1 1 2013

K130758

510(K) SUMMARY

as required by 807.92

Date:	Dec. 6, 2013
Submitter:	Kronner Prototypes, Inc. 1443 Upper Cleveland Rapids Road Roseburg, OR 97471 Tel: (541- 672-2543
ER Number:	3018984
Contact:	Richard F. Kronner M.D. President Telephone: (541) 672-2543 Fax: (541) 672-1074 E-mail: kronner@rosenet.net
Subject Device:	Trade Name: Kronner Side-Kick Uterine Manipulator Holder Common Name: Holder, Positioner, Arm, Instrument Guide Classification Name: no known industry name for this device Device Class: Unclassified (LKF)

Predicate Device: Intuitive Surgical (K071405) marketed as:
Coopers Uterine Positioning System by Coopersurgical
K071405

Device Description:

The Kronner Side-Kick uterine manipulator holder is used to mount, position and hold
in position uterine or vaginal manipulators used in laparoscopic surgical procedures. It is made mostly from aluminum and stainless steel and is mounted to standard operating room tables and locked in position allowing surgical devices to be securely held in position for long periods of time. Use of the Sidek-Kick frees operating room staff for other activities and reduces fatigue associated with manually maintaining a device in position during surgical procedures.

The manipulator is inserted into the patient using standard technique, then the Side-Kick is joined to the manipulator.

With proper adapters the Side-Kick may be used with various manipulators, such as the RUMI, the V-Care and the Arch Koh,

A gas supply module, which can be attached to the operating table rail, transfers nitrogen or compressed air from the wall or a portable tank to the Side-Kick holder through two flexible lines. When the switch is turned on the Side-Kick joints are locked. When the switch is turned off the Side-Kick joints are unlocked.

Pressing a foot pedal releases all the Side-Kick joints for position changes. When the foot pedal is released the joints lock. The foot pedal is connected to the gas supply module through two lines covered by a protective hose.

A branched gas line connects the two luers of the Arm assembly to the gas supply module. A single gas line connects the gas supply module to the main pivot.

The Kronner Side-Kick remains external to the patient's body at all times.

Intended Use:

The Kronner Side-Kick is intended to assist the surgical staff in mounting, positioning and holding a uterine manipulator during gynecological laparoscopic surgical procedures. It is intended for use by trained operating room personnel in an operating room environment.

"Caution: Federal law restricts this device to sale by or on the order of a physician.

Comparison to predicate device:

Based on the comparison of design, technology, materials, manufacturing, performance, specifications, and method of use, the Kronner Side-Kick is substantially equivalent to the previously identified pre-amendment and 510(k) cleared predicate device.

Technological Characteristics:

The technological characteristics of the subject device are the equivalent to the predicate devices.

Performance data:

Design analysis and testing has been conducted to confirm that basic functional characteristics of the subject device is substantially equivalent to the predicate device cited, and that design output meets the design input requirements.

Conclusion:

Based upon available technical information, intended use and performance information provided in this pre-market notification, the Kronner Side-Kick described herein is substantially equivalent to current legally marketed pre-amendment and 510(k) cleared predicate devices.

Kronner Sidekick Factory Testing

Kronner Sidekick and Sidekick uterine manipulator adapters are factory tested so they meet the following acceptance criteria:

1. That Arch Koh, RUMI, and V care manipulators can be attached to Sidekick adapters satisfactorally and can be used, as required, for the intended use .

2. That Arch Koh, RUMI, and V care manipulators will be able to move the uterus through a range required for the surgery.

3. That Arch Koh, RUMI, and V care manipulators will be held with the strength required for holding the uterus during the surgery.

4. That all Sidekick components will perform as required.

5. That all Sidekick components can be easily assembled in an operating room environment.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-002

Kronner Prototypes, Inc.
Richard F. Kronner, M.D.
1443 Upper Cleveland Rapids Road
Roseburg, Oregon 97471

December 11, 2013

Re: K130758
Trade/Device Name: Kronner Side-Kick Uterine Manipulator Holder
Regulatory Class: Unclassified
Product Code: LKF
Dated: October 23, 2013
Received: November 01, 2013

Dear Dr. Kronner:

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 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,

Joshua C. Nipper -S

For Binita Ashar, MD, MBA, FACS
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K130758

Statement of Indications for Use

510(k) Number (if known):_____

Device Name: Kronner Sidekick Uterine Manipulator Holder

Indications For Use:

For holding uterine manipulators during laparoscopic or open surgery on female pelvic organs.

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

CONCURRENCE OF CDRH, OFFICE OF DEVICE EVALUATION (ODE)

Prescription Use _____xx____ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

Long H. Chen -A Digitally signed by Long H. Chen -A DN: cn=Long H. Chen -A, ou=FDA, ou=People, ou=HHS, o=U.S. Government, c=US, 0.9.2342.19200300.100.1.1=1300369056 Date: 2013.12.10 06:41:59 -05'00' for BSA

(Division Sign-off)
Division of Surgical Devices
510(k) Number: K130758

(Optional Format 1-2-96)