

SEP 10 1997

K973259
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510(k) Summary

1. Submitter's Name, Address and Telephone Number, and Contact Person:

Perk Crook
Medical Creative Technologies, Inc.
2950-N Advance Lane
Colmar, PA 18915

Telephone: (215) 997-9689

Contact Person: Perk Crook

2. Name of the Device, including the trade or proprietary name if applicable, and the common name, and the classification name, if known:

Trade Name: K&W 2-Piece Take-Apart Instruments

Common Name: Endoscopic Forceps/Graspers/Scissors

Classification Name: Endoscopic and Accessories

3. Identification of the legally marketed device that the submitter claims equivalence:

The devices in consideration are substantially equivalent to the devices currently marketed by Karl Storz Endoscopy America, Inc., under 510(k) K952149.

4. A description of the device that is the subject of the premarket notification submission, such as might be found in the labeling or the promotional material of the device:

The K&W 2-Piece Take-Apart Instrumentation are endoscopic instruments which have jaws designed to cut, grasp, dissect, retract, and manipulate. The reusable handles are offered in both insulated and noninsulated actuating rings that adapt to various interchangeable jaw configurations with integral shafts. The shaft of the jaws fits into the handle and can be taken apart for cleaning. The jaws are rotated by turning the knob on the handle.

5. A statement of the intended use of the device that is the subject of the premarket notification:

The K&W 2-Piece Take-Apart Instrumentation is designed to be used endoscopically through cannulae to perform cutting, grasping, dissecting, retracting, and manipulating functions.

6. If the device has the same technological characteristics as the predicate device identified in paragraph (a)(3) of this section, a summary of the technological characteristics of new device in comparison to those of the predicate device; if the device has different technological characteristics from the predicate device, a summary of how the technological characteristics of the device compare to the legally marketed device:

The intended uses of the K&W 2-Piece Take-Apart Instrumentation and the Karl Storz Endoscopy America, Inc. Devices under K952149 have the same intended use, and that is for endoscopy procedures through cannulae for cutting, grasping, dissecting, retracting, and manipulating.

The devices have reusable handles that accommodate inserts, that can be rotated 360 degrees during use.

Both devices include insulated and noninsulated handles, and accommodating shafts.

In the K&W device there is included flushing port to facilitate cleaning. This port

is not present on the Karl Storz devices.

All K&W device handles adapt the interchangeable working ends by inserting them through the inner diameter of the shaft that is an integral port of the handle. The fit is secured by a detented proximal end that locks securely in place by encapsulation with the actuation of a push button. In some of the Storz instruments, security is achieved by a one-quarter turn into the outer tube and then connecting into the outer tube handle. The rest of the Storz instruments are the same as K&W.



SEP 10 1997

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850Ms. Perk Crook
Official Correspondent
Medical Creative Technologies, Inc.
2950-N Advance Lane
Colmar, Pennsylvania 18915-9727Re: K973259
K&W Two-Piece Take-Apart Instrumentation
Dated: August 26, 1997
Received: August 29, 1997
Regulatory class: II
21 CFR §876.1500/Product code: 78 KOG

Dear Ms. Crook:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsmamain.html>.

Sincerely yours,

Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

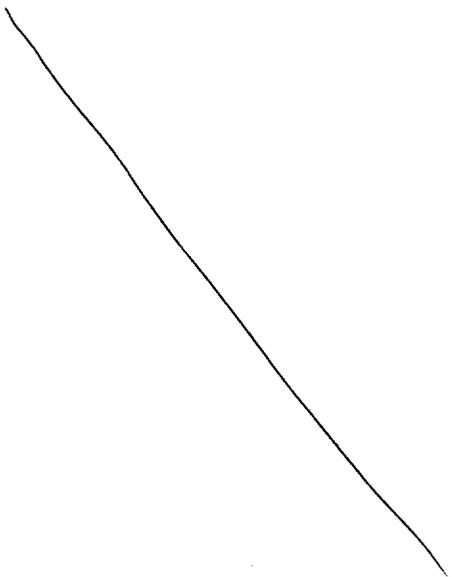
Enclosure

510(k) Number (if known): K973259

Device Name: 2-Piece Take-Apart Instruments

Indications For Use:

For use in endoscopic surgical procedures through cannulae to perform cutting, grasping, dissecting, retracting, and manipulating functions.



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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Robert R. Rathjens
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K973259

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)