

K981611

JUL 30 1998

510(k) Summary: #K981611**CIRCON SURGITEK Snap-N-Peel™ Introducer
(Introducer Sheath & Dilator)**

- 1) **Name of Submitter:** CIRCON SURGITEK Division of Circon Corporation

Address: 3037 Mount Pleasant Street
Racine, WI 53404

Telephone: (414) 639-7205

Contact Person: Dr. Ronald J. Ehmsen
Vice President, Regulatory Affairs
Circon Corporation
6500 Hollister Avenue
Santa Barbara, CA 93117

Telephone: (805) 961-3290
Fax: (805) 968-7385

Date Submitted: July 14, 1998

- 2) **Name of Device:** Introducer Sheath and Dilator

Proprietary/Trade Name: Snap-N-Peel™ Introducer

Common/Usual Name: Introducer Sheath and Dilator

Classification: Various (see attached table)

Classification Names: Various (see attached table)

- 3) **Name of Predicate or Legally Marketed Device:**

The CIRCON SURGITEK Snap-N-Peel™ Introducer is substantially equivalent to the Cook Peel-Away® Introducer that was approved by FDA for marketing on October 18, 1996, under 510(k) No. K961904, and to the Microvasive® Banana Peel™ Sheath that was approved by FDA for marketing on July 23, 1997, under 510(k) No. K971165.

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4) **Description of Device:**

The CIRCON SURGITEK Snap-N-Peel™ Introducer consists of a stepped dilator (with proximal Luer hub) that fits within an external sheath (with rotating locking collar). The dilator may be straight or curved and has a lumen to allow passage of fluids or a guidewire.

5) **Intended Use of Device:**

CIRCON SURGITEK's Snap-N-Peel™ Introducers are intended to be used to permit direct passage of catheters or other devices for the purpose of performing diagnostic and surgical procedures (e.g., nephrostomy, cystoscopy, ureteroscopy, etc.) in the urinary tract.

6) **Comparison of Technological Characteristics:**

CIRCON SURGITEK's Snap-N-Peel™ Introducers are substantially equivalent¹ to the legally marketed Cook Peel-Away® Introducers and the Microvasive® Banana Peel™ Sheaths. CIRCON SURGITEK's devices employ the same design considerations, materials of construction and operating principles. The CIRCON SURGITEK devices also employ lengths, diameters, and smoothly finished contours similar to those of the predicate devices and are supplied sterile, for single use. Any differences between the CIRCON SURGITEK and Cook or Microvasive devices do not raise new questions regarding safety or effectiveness. None of the devices actively delivers any form of energy to the patient.

¹The term, "substantially equivalent," is intended to reflect a determination of substantial equivalence under the Federal Food, Drug, and Cosmetic Act, and relates to the fact that the product can be marketed without premarket approval or reclassification. Such a determination is not intended to have any bearing on matters relating to patents.

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Classification Names

| CDRH Standard Product Nomenclature | Product Code | Class |
|---|-------------------------|--------------|
| Catheter, Nephrostomy | 78LJE | II |
| Catheter, Nephrostomy, General & Plastic Surgery | 79GBO | I |
| Catheter and Tube, Suprapubic | 78FEZ | II |
| Catheter, Suprapubic and Accessories | 78KOB | II |
| Catheter, Ureteral, Gastro-Urology | 78EYB | II |
| Catheter, Ureteral, General & Plastic Surgery | 78GBL | II |
| Catheter, Urethral | 78GBM | II |
| Catheter, Urological | 78KOD | II |
| | | |
| Dilator, Catheter | 79GCC | I |
| Dilator, Catheter, Ureteral | 78EZN | II |
| Dilator, Urethral | 78KOE | II |



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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ronald J. Ehmsen, Sc.D.
Vice President, Regulatory Affairs
Circon Corporation
6500 Hollister Avenue
Santa Barbara, California 93117

Re: K981611
Trade Name: Snap-N-Peel Introducers
Regulatory Class: II
Product Code: KNY
Dated: May 4, 1998
Received: May 6, 1998

Dear Dr. Ehmsen:

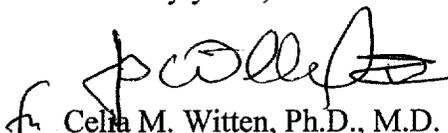
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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) 594-4595. 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,


Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Device Name: CIRCON SURGITEK Snap-N-Peel™ Introducers

Indications for Use:

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

OR

Over-The-Counter Use _____ (Optional Format 1-2-96)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number _____

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