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510(k) Summary
Conveen® EasiCath Set

NOV - 6 1997

Coloplast Corporation
1955 West Oak Circle
Marietta, Georgia 30062-2249
Date: August 15, 1997

1. **Contact Person**

Ms. Sydney Lilly, (770) 426-6362

2. **Name of the Medical Device**

Classification name:	Urological catheter and accessories
Common/usual name:	Intermittent Catheter
Proprietary name:	Conveen® EasiCath Set

3. **Device Classification**

The Conveen® EasiCath Set has been classified by the FDA under the heading of Urological catheter and accessories as a Class II device.

4. **Statement of Substantial Equivalence**

The Conveen® EasiCath Set is substantially equivalent to the O'Neil Urinary Catheterization System™ manufactured by Medical Marketing Group, Inc. K910022.

5. **Intended Use**

The Conveen® EasiCath Set is indicated for use by patients for intermittent catheterization for the purpose of bladder drainage.

6. **Description of Device**

The Conveen® EasiCath Set is a single use, disposable system that consists of a sterile polyvinylchloride intermittent catheter, coated with polyvinylpyrrolidone, and a sterile saline solution ampoule all sealed in a urine collection bag. The user twists open the saline ampoule inside the bag and soaks the catheter for 30 seconds. Once wet, the polyvinylpyrrolidone layer binds water molecules to the surface of the catheter creating a smooth lubricating film. The bag is opened and the catheter is inserted into the patent's urethra. The catheter itself is the same design and materials as our current non-coated Conveen® Intermittent Catheters, K896729.

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A comparison Matrix for the EasiCath Set versus the Medical Marketing Group, Inc. O'Neil Urinary Catheterization System™ is presented below.

	Conveen® EasiCath Set	Medical Marketing Group, Inc. O'Neil Urinary Catheterization System™
510(k) Number		K910022
Device composition	Polyvinylchloride catheter coated with polyvinylpyrrolidone, and sterile saline solution sealed in a urine collection bag.	Polyvinylchloride catheter coated with silicone sealed in a urine collection bag.
Sizes	Female Straight Ch. 8, 10, 12, & 14. Nelaton Ch. 8,10, 12, 14, 16, & 18. Pediatric Ch. 6, 8, & 10.	Female Straight - Sizes 6, 8,10, 12, 14, & 16 FR.
Function of device	Inserted into urethra through urinary tract till catheter reaches bladder and allows urine to drain.	Inserted into urethra through urinary tract till catheter reaches bladder and allows urine to drain.
Indication for use	For intermittent catheterization for the purpose of bladder drainage.	For intermittent catheterization for the purpose of bladder drainage.
Features of device	Coated catheter and saline ampoule sealed in urine collection bag.	Silicone coated catheter sealed in urine collection bag with silicone applicator tip. Kit includes povidone iodine swabs, gloves, underpad and tissue.
Sterilization	Sterile	Sterile
Packaging	Peel Pack	Peel Pack

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7. **Summary of Safety Testing**

A summary of the safety testing performed on the final sterile PVP coated catheter is listed below:

Test	Conclusion
Intracutaneous Test	No difference in skin reaction was observed at the injection sites of the extracts or the control solutions. Passed the Intracutaneous Test according to USP XXII requirements.
Systemic Injection Test	No signs of toxicity were observed in the mice treated with the extract or the control solution. Passed the Systemic Injection Test according to USP XXII requirements
Mutagenicity Ames Test	The extracts induced no increase in the number of revertants as compared to the controls. Thus, no detectable mutagenic activity was found of the extracts in the Ames test.
Sensitization Guinea Pig Maximization Test	No evidence of delayed contact hypersensitivity was seen after treatment with the extract or the control solution.
Cytotoxicity elution Test (L 929 cells)	Passed the Elution Test according to USP XXII requirements (cytotoxicity grade $\leq$ 2)

Polyvinylpyrrolidone is used in a number of medical devices that are commercially available in the U.S. Including Neurointerventional and Gastro-enteral Guidewires, Enteral Feeding Tubes, Urinary Stents, and Cannula for port access heart procedures.

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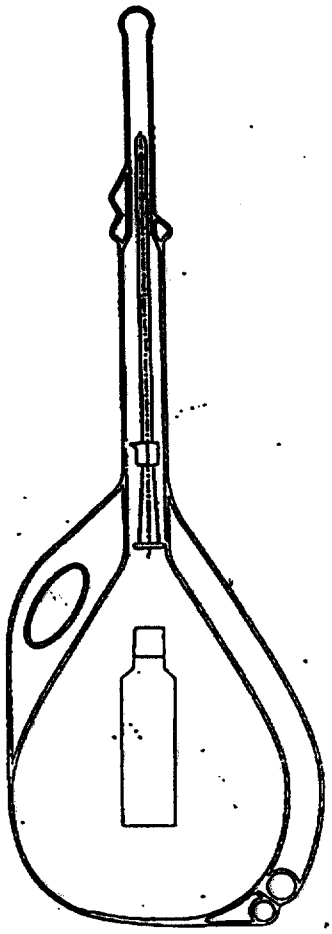
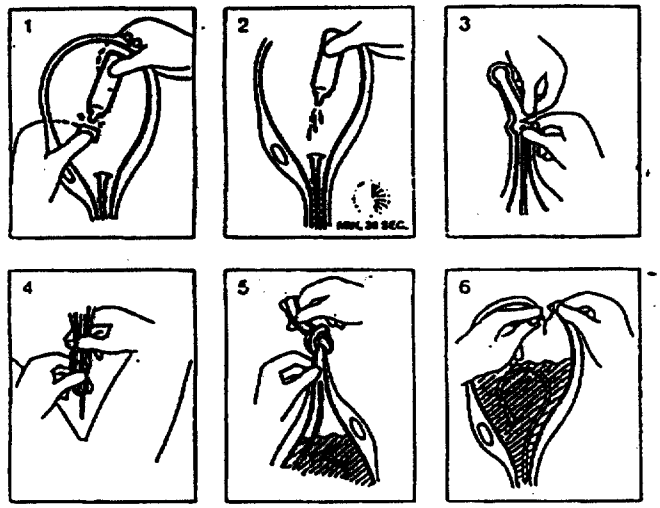
Figure 1
EasiCath Set Descriptive Drawings:

Conveen EasiCath Set





DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV - 6 1997

Ms. Sydney Lilly
Quality Assurance & Regulatory Affairs Manager
Coloplast Corporation
1955 West Oak Circle
Marietta, Georgia 30062-2249

Re: K973070
Conveen® EasiCath Set
Dated: August 15, 1997
Received: August 18, 1997
Regulatory class: II
21 CFR §876.5130/Product code: 78 EZD
21 CFR §876.5250/Product code: 78 KNX

Dear Ms. Lilly:

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): K973070

Device Name: Conveen® EasiCath Set

Indications For Use:

The Conveen® EasiCath Set is indicated for use by patients for intermittent catheterization for the purpose of bladder drainage.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Robert P. Sattler

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K973070

Prescription Use ✓ OR Over-The-Counter Use ____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)