

K970595

P173

SUMMARY OF SAFETY AND EFFECTIVENESS
Circon Endotek OM-4 Cystometry Pump

OCT 24 1997

Applicant's Name, Address and Establishment Registration Number:

Circon Corporation
6500 Hollister Avenue
Santa Barbara, CA 93117-3019
Establishment Registration Number 2020483

Owner/Operator's Name, Address, and Establishment Registration Number:

Circon Corporation
6500 Hollister Avenue
Santa Barbara, CA 93117-3019
Establishment Registration Number 2020483

Contact Person, Contact Person's Address and Telephone Number

Todd J. Polk
Circon Corporation
6500 Hollister Avenue
Santa Barbara, CA 93117-3019
Establishment Registration Number 2020483
Telephone (805) 961-3290

Manufacturing Site, Address and Establishment Registration Number:

Circon Corporation
6500 Hollister Avenue
Santa Barbara, CA 93117-3019
Establishment Registration Number 2020483

Device Trade/Proprietary Name and Catalog Number:

Catalog No.	Description
Not Assigned	Circon Endotek OM-4 H ₂ O Cystometry Pump
Not Assigned	H ₂ O Cystometry Pump Interconnecting Cable
5290700	Ultra Pump H ₂ O Infusion Set (10/case)

Summary of Safety and Effectiveness: Circon Endotek OM-4 H₂O Cystometry Pump

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Classification Name and Panel Classification Number:

Product Nomenclature	Device, Cystometric, Hydraulic
Classification Name	Urodynamics Measurement System
Procode	78 FEN
Regulation Number	21 CFR § 876
Classification	Class II (Special Controls)
Device Common or Usual Name	H ₂ O Cystometry Pump

Performance Standards:

No applicable performance standards have been promulgated under Section 514 of the Medical device Act for Cystometric Measuring Systems.

The OM-4 H₂O Cystometry Pump is designed to meet the following voluntary standards:

Designed to Meet Following Safety Specifications Electrical Spillage Package Drop Test	UL 2601, CSA 601, IEC 601-2 BSI NSTA
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Marketed Devices Used for Substantial Equivalence

Manufacturer	Model No.	Description	510(k) No.
Circon Endotek	Ultra System	Cystometric Measuring System	K920451
Browne	MiniPro 8100	Cystometric Measuring System	K921047
Browne	Profile Plus	Cystometric Measuring System	K920992
WEST	MERKUR 4000	Cystometric Measuring System	K920575

Device Description and Intended Use of the Marketed Device

The Circon Endotek OM-4 H₂O Cystometry Pump is a peristaltic pump used with the Circon Endotek OM-4 Urodynamics Monitoring System for pressurizing the filling media during cystometry measurements.

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Indicated Use for the Proposed Device

The Circon Endotek OM-4 Urodynamics Monitoring System is indicated for urodynamic diagnostic procedures only. It is to be operated only by qualified physicians or qualified personnel under the direction and supervision of a physician trained in urodynamic monitoring techniques.

The Circon Endotek OM-4 H₂O Cystometry Pump is used to pressurize the filling media during water cystometry diagnostic procedures. The device is designed to be used with the Circon Endotek OM-4 Urodynamic Monitoring System.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 24 1997

Mr. Andrew D. Simon
Vice President Secretary
Circon Corporation
6500 Hollister Avenue
Santa Barbara, California 93117-3019

Re: K970595
Circon Endotek OM-4 H₂O Cystometry Pump
Dated: August 15, 1997
Received: August 19, 1997
Regulatory class: II
21 CFR §876.1620/Product code: 78 FEN
21 CFR §876.1800/Product code: 78 EXY

Dear Mr. Simon:

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): Not Assigned *K 970595*

Device Name: Circon Endotek OM-4 H₂O Cystometry Pump

Indications For Use:

The Circon Endotek OM-4 Urodynamics Monitoring System is indicated for urodynamic diagnostic procedures only. It is to be operated only by qualified physicians or qualified personnel under the direction and supervision of a physician trained in urodynamic monitoring techniques.

The Circon Endotek OM-4 H₂O Cystometry Pump is used to pressurize the filling media during water cystometry diagnostic procedures. The device is designed to be used with the Circon Endotek OM-4 Urodynamic Monitoring System.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Robert R. [Signature]

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number *K 970595*

Prescription Use
(Per 21 CFR 801.109)

OR

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