K051206
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510(k) SUMMARY INFORMATION

APPLICANT NAME:	Moss Medical Products, Inc.
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FAX:	914-684-1464
E-MAIL:	mosstube@mossmed.com
ACTIVITY OF APPLICANT	Initial Distributor
CONTACT PERSON:	GERALD MOSS, Ph.D., M.D.
ADDRESS:	1 Reynal Road White Plains, New York 10605
PHONE:	914-997-0392
FAX:	914-684-1464
E-MAIL:	gerald_moss@mossmed.com
NAME OF DEVICE	
TRADE NAME:	Y2K2 Enteral Tube Fluid Filter
COMMON NAME:	In-Line Filter
CLASSIFICATION NAME:	***{21 CFR 876.5980}*** ***{Tubes, Gastrointestinal (and accessories)}***
PRODUCT CODE:	***{KNT}***
MANUFACTURER:	Filtertek, Inc. P.O. Box 310 11411 Price Road Hebron, IL 60034-0310
PREDICATE DEVICES:	Pall PharmAssure Capsule Filter (K943127) Cobe Cardiovascular Pre-bypass Filter (K850139)

INDICATIONS FOR USE: The device will filter fluids to be delivered into a feeding tube to remove potentially obstructing particulates.

TECHNICAL CHARACTERISTICS: The proposed and predicate devices are of essentially the same size, construction, and function. They are made of comparable (Re: Pall) or identical (Re: Cobe Cardiovascular) inert biomaterials. The Y2K2 Enteral In-Line Filter differs in having a larger pore size, to remove coarse (but not fine) particulates from enterally delivered fluids.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Moss Medical Products, Inc.
c/o Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services LLC
1394 25th Street NW
BUFFALO MN 55313

Re: K051206
Trade/Device Name: Y2K2 Enteral In-Line Filter
Regulation Number: 21 CFR §876.5980
Regulation Name: Gastrointestinal tube and accessories
Regulatory Class: II
Product Code: 76 KNT
Dated: October 15, 2005
Received: October 17, 2005

Dear Mr. Job:

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.

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 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); 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.

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K051206

Indications for Use

510(k) Number (if known): K051206

Device Name: Y2K2 Enteral In-Line Filter

Indications For Use:

The Y2K2 Enteral In-Line Filter is intended for use to filter liquid feeding solutions prior to delivery into a patient's pre-inserted feeding tube, to minimize the risk of tube occlusion by macro particulates.

This will be applicable to any size or length pediatric or adult feeding tube (e.g., nasogastric, nasoduodenal, nasojejunal, gastrostomy, jejunostomy, transgastric duodenal, or transgastric jejunal).

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Lepmm

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K051206