TAB 4. 510(k) SUMMARY INFORMATION

NAME:	Moss Medical Products, Inc.
ADDRESS:	4049 NY 150 West Sand Lake, NY 12196
PHONE: FAX: E-MAIL:	518-674-0904 914-684-1464 mosstube@mossmed.com
ACTIVITY OF APPLICANT	Initial Distributor
CONTACT PERSON:	GERALD MOSS, Ph.D., M.D.
ADDRESS:	1 Reynal Road White Plains, NY 10605
PHONE: FAX: E-MAIL:	914-997-0392 914-684-1464 gerald_moss@mossmed.com
NAME OF DEVICE TRADE NAME: COMMON NAME: CLASSIFICATION NAME:	 MossMed Dual Intermittent Aspirator Suction Controller 21 CFR 878.4780 Powered Suction Pump
PRODUCT CODE:	KNT
MANUFACTURER:	Hudson Research, Inc. 461 Pinebrook Boulevard New Rochelle, NY 10804
PREDICATE DEVICE:	Continuous & Programmable Intermittent Aspirator – Impact Instrumentation, Inc. (K951423)
INDICATION FOR USE:	The intended use of the device is to convert regulated continuous suction to "intermittent suction" appropriate for aspiration of gastro-intestinal fluid into two separate chambers that are reversed in on/off phases. This permits gravity "refeeding" of the aspirate during the "off" phases of each chamber's cycle, while maintaining "continuous suction" on the aspiration tube.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB - 5 2004

Gerald Moss, Ph.D., M.D.
President
Moss Medical Products, Inc.
4049 NY 150
WEST SAND LAKE NY 12196

Re: K031492
Trade/Device Name: MossMed Dual Intermittent Aspirator
Regulation Number: 21 CFR §876.5980
Regulation Name: Gastrointestinal tube and accessories
Regulatory Class: II
Product Code: 78 KNT
Dated: November 6, 2003
Received: November 7, 2003

Dear Dr. Moss:

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 (PMA), it may be subject to 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 the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

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" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained 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/dsma/dsmamain.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

Indications for Use

510(k) Number (if known):
K031492

Device Name:
Moss Medical Products, Inc. Dual Intermittent Aspirator

Indications For Use:

The proposed device interrupts externally supplied continuous suction to individually provide "intermittent suction" to one or two aspiration catheters positioned in the patient's gastrointestinal tract.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K031492