

DEC 19 2003

K031436
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SOMETECH CORPORATION
6669 PEACHTREE INDUSTRIAL BOULEVARD, SUITE J
NORCROSS, GEORGIA 30092

TEL: 770-825-0100 **FAX: 770-849-9733**

SUMMARY OF SAFETY AND EFFECTIVENESS

APPLICANT'S NAME/ADDRESS	SOMETECH INC. JUNGIL B/D 6F 142-2 NONHYUN-DONG KANGNAM-GU SEOUL 135-010 SOUTH KOREA
CONTACT PERSON:	Mr. Ki Cheol Han
TRADE NAME:	MEDISCOPE
COMMON/USUAL NAME:	COLPOSCOPE (AND COLPOMICROSCOPE)
CLASSIFICATION NAME:	COLPOSCOPE (AND COLPOMICROSCOPE)
OWNER OPERATOR #:	9057673
CLASSIFICATION:	CLASS II UNDER 21 CODE OF FEDERAL REGULATION 884.1630
PERFORMANCE STANDARD:	MEDISCOPE MEETS ALL DESIGN SPECS AND IS EQUIVALENT TO THE PREDICATE DEVICE.

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SUBSTANTIAL EQUIVALENCE:

SOMETECH INC. BELIEVES THE MEDISCOPE IS SUBSTANTIALLY EQUIVALENT TO THE WELCH ALLYN COLPOSCOPE/VERTICAL ROLLING BASE/SWING ARM (510 (K) NUMBER K955635).

MEDISCOPE, colposcope (Obstetrical and Gynecological Diagnostic Device) is a medical camera unit and accessories to be used to magnify and view tissues of the cervix and diagnose abnormalities and select areas for biopsy. Mediscope consists of a main unit (power source) and probe.

MEDISCOPE is designed for effective communication and education between doctors and patients.

MEDISCOPE can be connected to a TV, CCTV, or Color Video Printer.

MEDISCOPE has undergone various electrical safety tests and has met the following standards.

1. IEC 60601-1, Medical electrical equipment – Part 1 : General requirements for safety.
2. En 60601-1-2, Standard for Electromagnetic Compatibility.

In summary, MEDISCOPE meets or exceeds all safety requirements for a medical device in its class. Our dedication to safety is evidenced in the many steps we have taken to insure a safe product.



DEC 19 2003

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Ki Cheol Han
President
Somotech Corporation
6669 Peachtree Industrial Blvd.
Suite J
NORCROSS GA 30092

Re: K031436
Trade/Device Name: MEDISCOPE
Regulation Number: 21 CFR §884.1630
Regulation Name: Colposcope
Regulatory Class: II
Product Code: 85 HEX
Dated: September 16, 2003
Received: September 22, 2003

Dear Mr. Han:

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.

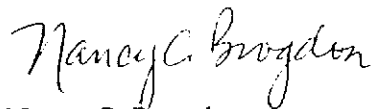
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to 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
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

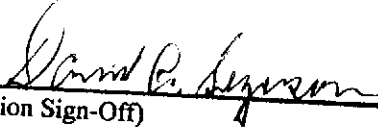
Indications for Use Statement

PMN 510(k) Number: K031436

Device Name: MEDISCOPE
(Colposcope (And colpomicroscope))

Indication for Use:

MEDISCOPE, colposcope (Obstetrical and Gynecological Diagnostic Device), is intended for magnified viewing of the tissues of cervix.



(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices

510(k) Number K031436

Prescription Use _____
(Per 21 CFR 801.109)