

SEP 14 1998

K981143

Contract: Margaret Blackmore

4 September 1998.

Ref: K981143

SUMMARY OF SAFETY AND EFFECTIVENESS

Trade Name: Dilkes Laser/Suction Cannulae

Common Name: Twin Channel Suction Tube

Classification Name: Unknown

Predicate Devices:

1. House Suction/Irrigation Tube 55-0207, manufactured by Richards.
2. Microstat hand-piece from Laserscope

Description of Device: This device is constructed from an Exmoor Single Use Suction Tube (MP17291), 510K 892504, a piece of stainless steel needle tubing (MP170288) identical to that used in MP170291, covered by the same 510K 892504, and a piece of silicone rubber tubing (MP180163) which is used to hold the two pieces of stainless steel tubing together in the correct position. It uses locally supplied suction tubing to connect the device to suction by pushing the tubing over the ball feature at the proximal end of the handle. The laser fibre is passed down the exposed end of the stainless steel tubing adjacent to the handle until it emerges from the distal end. The laser fibre protruding from the distal end of the instrument should be stripped and cleaved and adjusted to the required length.

Intended Use: Any surgical procedure within the nasal cavity, the oral cavity or the oropharynx, which requires laser surgery and suction capability to remove smoke.

Comparison with Predicate Devices: The size of the House Suction/Irrigation Tube is very similar to the Dilkes Laser/Suction Cannulae.

The predicate device is currently being used for suction/laser delivery.

The materials are similar in that stainless steel is used in both cases. The handle of the subject device is polyethylene, as this is a single-use device. The predicate device is re-usable.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 14 1998

Ms. Margaret Blackmore
Regulatory Affairs Administrator
Exmoor Plastics Limited
Lisieux Way
Taunton, TA1 2LB, U.K.

Re: K981143
Trade Name: Dilkes Laser/Suction Cannulae
Regulatory Class: II
Product Code: GEX
Dated: August 5, 1998
Received: August 11, 1998

Dear Ms. Blackmore:

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.

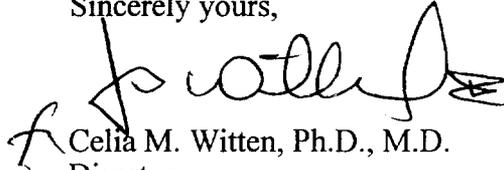
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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.

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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) 594-4595. 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,

A handwritten signature in black ink, appearing to read "Celia M. Witten", with a stylized flourish at the end.

Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K981143

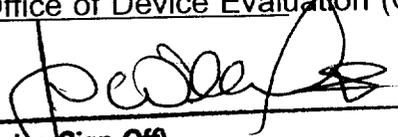
Device Name: DILKES LASER/SUCTION CANNULAE

Indications for Use:

Any surgical procedure within the nasal cavity, the oral cavity or the oropharynx, which requires laser surgery and suction capability to remove smoke.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of General Restorative Devices K981143
510(k) Number _____

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)