JUL 17 2003

10.0 510(k) Summary

K030158

a. Submitter Information

Walsh Medical Devices Inc.
1200 South Service Road, W, Unit 3
Oakville ON L6L 5T7

Telephone:	(905) 844-8344
Fax:	(905) 338-0488
Contact Person:	David Stiles Director of Quality Systems
Date Prepared:	November 20, 2002

b. Device Identification

Common/Usual Names:	Cautery Handles & Cautery Tips
Proprietary Name:	Walsh Medical Devices Inc. Cautery Handles & Cautery Tips
Device Classification:	**CLASS II**

c. Identification of Predicate Device(s)

The Walsh Medical Devices Inc. Cautery Handles and Cautery Tips are substantially equivalent to those offered by Aaron Medical Industries (K945761, k945762 & k945763) previously cleared and currently marketed.

d. **Device Description**

Battery powered Cautery Handles and Cautery Tips to coagulate tissue or arrest bleeding from small vessels using heat created by the wire tip during Ophthalmic, General and Plastic Surgery and Vasectomy procedures.

PRODUCT CODE #	DESCRIPTION
9671	Cautery Handle (MEDIUM TEMP) – 2 "AA" batteries
9672	Cautery Handle (LOW TEMP) – 1 "AA" battery
9675	Cautery Tip (Short)
9676	Cautery Tip (Medium)
9677	Cautery Tip (Vasectomy)
9678	Heavy Duty Cautery Tip (Long)

e. **Substantial Equivalence**

The Walsh Medical Devices Inc. Cautery Handles and Cautery Tips Units are substantially equivalent to the Cautery Handles and Tips offered by Aaron Medical Industries (k945761, k945762 & k945763), differences exist between these devices relating to technical specifications, materials, and physical appearance do not affect the relative safety or effectiveness of the Walsh Cautery Handles and Cautery Tips relative to the predicates.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 17 2003

Mr. David Stiles
Director of Quality Systems
Walsh Medical Devices, Inc.
1200 South Service Road, W, Unit 3
Oakville, Ontario L6L 5T7

Re: K030158
Trade/Device Name: Walsh Medical Devices, Inc. Cautery Handles & Cautery Tips
Regulation Number: 21 CFR 878.4400, 886.4100
Regulation Name: Electrosurgical cutting and coagulation device and accessories, Radiofrequency electrosurgical cautery apparatus
Regulatory Class: II
Product Code: GEI, HQR
Dated: May 13, 2003
Received: May 14, 2003

Dear Mr. Stiles:

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 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 (301) 594-4659. 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,

Miriam C. Provost

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

Enclosure

510 (k) NUMBER (IF KNOWN) : K030158

DEVICE NAME : WALSH MEDICAL DEVICES INC. CAUTERY HANDLES & CAUTERY TIPS

INDICATIONS FOR USE:

CAUTERY HANDLES AND CAUTERY TIPS ARE INTENDED FOR COAGULATING TISSUE OR ARRESTING BLEEDING FROM SMALL VESSELS USING HEAT CREATED BY THE WIRE TIP. INDICATIONS INCLUDE OPHTHALMIC AND GENERAL AND PLASTIC SURGERY PROCEDURES.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X (Per 21 CFR 801.109) OR Over-The-Counter-Use _____ (Optional Format 1-2-96)

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K030158