OCT - 8 1997

K972612

9. SMDA Summary of Safety and Effectiveness - "510(k) Summary"

A. Submittor Information

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Regulatory Affairs

Date Prepared: July 11, 1997

B. Device Identification

Common/Usual Name: Ultrasonic Surgical Aspirator
Proprietary Name: DISSECTRON

C. Identification of Predicate Device(s)

The DISSECTRON is substantially equivalent to the following previously cleared and currently marketing devices:

Cooper Cavitron CUSA 200M (K864943)
Sharplan 4300/4310 (K883091)
Clinical Technology BOVIE (K855138A)

D. Device Description

The DISSECTRON is an ultrasonically vibrating hand-held surgical aspirator designed to precisely fragment and emulsify unwanted neurosurgical tissue, layer by layer, with preservation of major blood vessels, nerves, and elastic fibers.

The DISSECTRON's selective effect on tissue is the result of three combined factors:

- Ultrasonic fragmentation,
- Irrigation, and,
- Suction.

The DISSECTRON's principle of operation is tissular fragmentation which is achieved through ultrasonic longitudinal vibrations at an oscillation amplitude varying from 120 to 300µm, at an operating frequency comprised between 23 and 35 kHz at the tip of the handpiece. The ultrasonic power is transmitted via a piezoelectric transducer, housed in the handpiece, which extends into a titanium sonotrode which is in direct contact with the tissue. It is possible to precisely dissect tissue with less surrounding tissue invasion and blood loss with DISSECTRON.

Simultaneous irrigation is provided to the distal end of the tip. Sterile saline is routed from the drip holder to the control unit to the tip of the electrostrictive handpiece.

A vacuum pump aspirates emulsified tissue in the pressure range of 650 hPa. Irrigating fluid and fragmented tissue particles are continuously aspirated through the distal end of the hollow titanium sonotrode (tip) and transported, via disposable tubing, to a collection bottle ("receptacle").

The DISSECTRON, a compact, portable, tabletop ultrasonic surgical aspirator installed in the surgical suite within the user's reach, consists of three primary components:

- the base console,
- the hand-piece unit, (with 2 sonotrode dedicated extensions, and,
- the control pedal (footswitch).

The base console is controlled by a microprocessor and provides various indicators and controls designed to lead the operator through the sequential procedures needed for safe operation. Touch screen controls and displays provide the surgeon with a user friendly device.

The lightweight electrostrictive handpiece is equipped with a titanium sonotrode, which acts as an ultrasonic transmitter, and is fitted with central suction and concentric irrigation.

The foot pedal has two footswitches, a right switch, and a left switch, respectively, to control the Suction, Irrigation, and Ultrasound power.

E. Substantial Equivalence

The technical characteristics are almost identical to those of Cooper Cavitron CUSA 200 M, the Sharplan 4300/4310, and the Clinical Technology BOVIE previously cleared predicate devices. Refer to Table A for a comparison of these predicate devices. Differences that exist between these devices relating to technical specifications, materials, physical appearance, and control systems, do not affect the relative safety or effectiveness of the DISSECTRON device.

The intended use for the DISSECTRON device, as with the previously cleared devices, is for the successful fragmentation, emulsification and aspiration of soft tissue of various extirpation of any tumor in the central nervous system, inclusive of intracranial tumors, brain stem tumors, and spinal cord tumors, and neuro-acoustic tumors, and not necessarily limited to the following:

- Astrocytoma
- Cerebellopontine anglo tumors
- Cervico-facial tumors
- Metastases
- Pituitary adenoma
- Acoustic neurimoma
- Meningioma
- Glioma
- Craniopharynglomas
- Deep-seated cerebral tumors

The DISSECTRON device is **not intended** for use in the following applications:

- any type of cardiac surgery,
- suction lipectomy,
- orthopedics

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20856

OCT - 8 1997

Ms. Jacqueline E. Masse
Senior Consultant
Interactive Consulting, Inc.
for Satelec Medical
70 Walnut Street
Wellesley, Massachusetts 02181

Re: K972612
Trade Name: DISSECTRON Portable Unit
Regulatory Class: Unclassified
Product Code: 84LBK
Dated: July 11, 1997
Received: July 14, 1997

Dear Ms. Masse:

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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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.

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) 594-4648. 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 at (301) 443-6597.

Sincerely yours,

Thomas J. Callahan

Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular, Respiratory,
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K972612

Device Name: DISSECTRON Portable Unit

Indications For Use:

Fragmentation, emulsification and aspiration of soft tissue in the neurosurgery field.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Thomas J. Callahan

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K972612

Prescription Use ✓ OR Over-The-Counter Use_____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)