JAN 16 1998

K972857

510(k) SUMMARY FOR MEDICON eG'S SERVOTRONIC EC 100

Submitter's Name, Address, Telephone Number, And Contact Person

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Date Prepared
June 26, 1997

Name of the Devices
Servotronic EC 100

Common or Usual Name
Microprocessor-Controlled Microsurgical System

Classification Name
Surgical Instrument Motors and Accessories/Attachments (21 C.F.R. § 878.4820)

Predicate Devices
Aesculap Microtron System

Intended Use

The Servotronic EC 100 System is intended to be used for high speed cutting, sawing, drilling, and manipulation of soft tissue and bone in microsurgical procedures including maxillofacial surgery, ENT surgery, orthopedic surgery, plastic surgery, dental surgery and neurosurgery.

Technological Characteristics

The Servotronic EC 100 System's primary components are: (1) a control unit with irrigation pump; (2) a micromotor; (3) a foot switch for remote control; and (4) various hand pieces and tools. The hand pieces to be used with the Servotronic EC 100 System include the following: (1) Sachse Micro Oscillating Saw; (2) Sachse

Micro Osseoscalpel Saw; (3) Micro Compass Saw; (4) Steinhauser Mucotome; (5) Micro Sagittal Saw; and (6) Hauenstein Angular Screwing Instrument.

The Servotronic EC 100 requires an AC current of 110V or 230/240V. An electrical cord, which is intended to be plugged into a standard electrical outlet, is connected to the back of the control unit. The Servotronic EC 100 has integrated safety and monitoring functions for excess temperature, current limitations within the main supply circuit and within the motor electronics, and a speed-dependent stop used during a change of direction.

Principles of Operation

Operation of the Servotronic EC 100 System is accomplished by setting different micromotor speeds, irrigation pump flow rate, and transmission/reduction ratios. Various hand pieces can be attached to the micromotor depending upon the procedure. Tools, such as saw blades and drills, are attached to the hand pieces. The micromotor transmits power to the hand pieces to be used in the manipulation of body tissue during microsurgical procedures.

The console houses a microprocessor and an irrigation pump motor. The buttons for setting the micromotor speed, transmission/reduction gear ratio, and irrigation pump flow rate are located on the front panel of the console. The switches that are used to start and stop the irrigation pump and the motor(s) and change the direction of rotation of the hand piece are located on the foot switch.

A standard saline solution bottle is attached to the bottle holder attached to the console with tubing connected to an irrigation pump. The tubing is then attached to a port on the micromotor and hand piece assembly. The saline solution flows through the tubing at the rate set by the operator to provide internal and external irrigation.

Summary of the Basis for the Finding of Substantial Equivalence

The Servotronic EC 100 and the predicate device have the same intended use and substantially equivalent principles of operation. The device is operated by setting the motor speed, transmission/reduction gear ratio, and the irrigation pump flow rate. The console and foot pedal have buttons to operate the hand piece and irrigation pump. The Servotronic and predicate device microprocessors implement the commands from operation of the foot pedal or console. Although there are some minor differences in their some characteristics, namely the range of micromotor speeds and the quantity of handpiece gear ratios, these differences do not present any new issues of safety or effectiveness. Thus, the Servotronic EC 100 is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 16 1998

Mr. Howard M. Holstein
Medicon, E.G.
C/O Hogan & Hartson, L.L.P.
555 Thirteenth Street, N.W.
Washington, DC 20004-1109

Re: K972857
Trade Name: Servotronic EC100 System
Regulatory Class: II
Product Code: HBC
Dated: October 30, 1997
Received: November 13, 1997

Dear Mr. Holstein:

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 requirements, 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.

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,

for 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): K972857

Device Name: Servontronic EC100 System

Indications For Use:

High speed cutting, sawing, drilling, and manipulation of soft tissue and bone in microsurgical procedures including maxillofacial surgery, ENT surgery, orthopedic surgery, plastic surgery, dental surgery, and neurosurgery.

(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
510(k) Number K972857

Prescription Use X OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)