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

K962087

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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 and Jedmed Fisch Drill 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, and plastic surgery.

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 Servotronics EC 100 and the predicate devices 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 devices.