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510(k) SUMMARY FOR THE STAT*IM* 5000 CASSETTE AUTOCLAVE

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Classification:	Sterilizer, Steam
Common/Usual Name:	Sterilizer, Steam
Trade/Proprietary Name:	STAT*IM* 5000 Cassette Autoclave
Establishment Registration Number:	8043629
Classification:	Class II under 21CFR880.6880

Statement of Intended Use

The STAT*IM* 5000 Cassette Autoclave is a table-top steam sterilizer designed for the reprocessing of reusable instruments in a clinical setting. The STAT*IM* 5000 has four microprocessor-controlled, pre-programmed cycles. The first cycle operates at 132 °C for 3.5 minutes and is used for light loads of up to 0.5 kg solid stainless steel instruments free from deep cavities or holes, for example, scalers, forceps or scissors. The second cycle operates at 132 °C for 6 minutes and is for up to 1.5 kg of stainless steel instruments, such as those described above, and instruments of more complex construction, such as handpieces, wrapped in paper/paper or paper/plastic-film packs. The third cycle operates at 121 °C for 35 minutes and is for up to 0.4 kg of rubber, plastic or heat-sensitive items, for example, plastic mouth mirrors, suction tips or impression trays. The fourth cycle is designed for up to 1.5 kg of unwrapped stainless steel instruments, such as those described above, and instruments of more complex construction, such as handpieces.

Predicate Device for Substantial Equivalence

The STAT*IM* 5000 Cassette Autoclave is similar in design, composition and function to the STAT*IM* Cassette Autoclave manufactured by SciCan, Division of Lux and Zwingenberger. The STAT*IM* has an approved 510 (k) application (K915054) and is currently being marketed in the USA. The main difference between the two autoclaves is that the STAT*IM* 5000 sterilization cassette is larger than the one in the STAT*IM*. The larger size cassette has necessitated changes to the cycle parameters and an increase in the overall size of the unit. Both devices are table-top automatic steam autoclaves with the same electrical requirements. The monitored cycle parameters (time and temperature) are the same in both devices, and they are designed to process similar types of loads.

Technical Description

The STAT*/M* 5000 Cassette Autoclave is considered a fast, efficient table-top unit for the sterilization of health care instruments. The STAT*/M* 5000 uses the conventionally accepted parameters of saturated steam at temperatures of 132 °C and 121 °C for specific times depending on the cycle selected. The following chart shows the cycle types with the sterilization time, sterilization temperature, maximum load size and the number of purges in the conditioning phase. The conditioning phase is described later in this summary.

Program	Temperature	Sterilization Time	Maximum Load	Number of Purges
Unwrapped Instruments	132 °C	3.5 minutes	0.5 kg	1
Wrapped Instruments	132 °C	6 minutes	1.5 kg	6
Heavy Duty Unwrapped Instruments	132 °C	6 minutes	1.5 kg	1
Rubber and Plastics	121 °C	35 minutes	0.4 kg	3

Low power requirements (110 - 120 V, 11 A, 60 Hz and 1300 W) mean that the unit can be plugged into a grounded 15 A, 110 V circuit.

The dimensions of the STAT*/M* 5000 are 21 3/4" (length) x 16 1/4" (width) x 7 1/2" (height). The internal dimensions of the cassette are 15" (length) x 7" (width) x 3" (height).

There is an optional built-in printer which provides a record of the cycle parameters. Printed data includes time and date, cycle count, cycle chosen, the start time of each cycle phase, the temperature and pressure at 30 second intervals during the sterilization phase and error conditions encountered. The printer pressure is calculated, not measured.

The STAT*/M* 5000 features a removable stainless steel cassette, which, when inserted into the insulated steel receptacle, forms the sterilization chamber. The cassette consists of a lid (including user-replaceable seal) and a tray. Sockets at the rear of the cassette connect to a steam line and exhaust valve upon insertion into the insulated receptacle. The cassette seal distributes steam from the rear of the cassette to the front, creating a wall of steam to remove air through the exhaust socket. The cassette is positioned to allow condensed steam to collect and drain through the exhaust socket to the exhaust valve.

During operation, distilled water is pumped according to the control algorithm into the steam generator. The saturated steam produced by the steam generator travels to the cassette through the steam socket. The steam temperature is monitored by two calibrated thermocouples, one located in the cassette chamber and the other in the steam generator. The cassette chamber thermocouple is located at the exhaust socket. Power to the steam generator is modulated by a microprocessor based control system in order to maintain the temperature in the cassette chamber. This process, along with internal baffles in the steam generator, ensure a supply of saturated steam at the appropriate temperature into the cassette chamber.

The STAT*IM* 5000 has four microprocessor controlled sterilization cycles. The first cycle sterilizes at 132 °C for 3.5 minutes and is for unwrapped stainless steel instruments. The second cycle sterilizes at 132 °C for 6 minutes and is for wrapped stainless steel instruments. The third cycle sterilizes at 121 °C for 35 minutes and is for rubber and plastic instruments. The fourth cycle sterilizes at 132 °C for 6 minutes and is for large loads of unwrapped stainless steel instruments.

Each of the cycles includes six phases: 1) warm-up, 2) conditioning, 3) pressurizing, 4) sterilizing, 5) venting and 6) air-drying. During the first phase, the introduction of steam into the cassette purges the air through the open exhaust valve. Successive pulses of steam raise the temperature inside the cassette chamber to 132 °C or 121 °C, depending on the cycle selected, as the air continues to be purged. Depending on the cycle selected, the second phase consists of a series of deep purges, during which the exhaust valve opens until the temperature falls from the sterilization temperature of 132 °C or 121 °C to 110 °C or 115 °C, depending on the cycle selected. The exhaust valve closes and the unit repressurizes to the sterilization temperature. These purges expel the remaining air from the cassette. When the defined number of cycle dependent purges are completed, the third phase begins. The temperature inside the cassette rises to 132 °C or 121 °C, depending on the cycle selected, and the exhaust valve opens to expel condensate. The fourth phase begins when the desired sterilization temperature, 132 °C or 121 °C, depending on the cycle selected, is reached and continues for the required time period during which the sterilization temperature is maintained. At the end of this period the fifth phase begins. The exhaust valve opens and the pressure inside the cassette falls to atmospheric pressure and the cassette can be removed. If the cassette is not removed, or the stop button is not pressed, the sixth phase begins. In this phase, an air compressor flushes filtered air through the cassette chamber to dry and cool the instruments.

The safety and effectiveness problems which could affect the STAT*IM* 5000 are typical of all steam autoclaves. For example, caution must be exercised not to over-pack the autoclave, thereby inhibiting the free flow and even penetration of

steam. To ensure safety, every error condition is detectable by the unit and will result in an incomplete cycle and a warning on the display. The pressure vessel safety aspects are less serious in the STAT*IM* 5000 than in other typical table-top sterilizers because the STAT*IM* 5000 has no door hinge mechanism which can fail or be partially closed, thereby preventing explosion hazards reported for pressure-cooker type autoclaves with front-hinged doors. The safety is further assured because of its small cassette volume and heavy gauge steel support structure. Other safety features include the detection of error conditions within the unit that are displayed for the user.

Physical Evaluation

Physical performance testing has been conducted and demonstrates that:

1. saturated steam is present in the sterilization chamber during the sterilization phase of each cycle; [a]
2. the sterilization temperature throughout the chamber is controlled to within -1/+3 °C of the specified sterilization temperature for each cycle; [b]
3. the sterilization exposure timing is accurate to within 5% of the stated time; [c]
4. the temperature indicator and recorder accuracy is within ±1 °C; [d]
5. the calculated pressure accuracy during the sterilization phase of each cycle is within ±15 kPa. [e]

The STAT*IM* 5000 Cassette Autoclave conforms to UL1262 and CSA C22.2-151M, both laboratory equipment safety standards.

Microbiological Evaluation

The STAT*IM* 5000 Cassette Autoclave was tested according to a microbiological protocol designed to demonstrate the efficacy with which the unit sterilizes a wide range of instruments. This protocol and report of test results have been submitted to the FDA, and are summarized below.

1. Culture media was evaluated for sterility, volume control, and growth promotion of low numbers of *Bacillus Stearothermophilus* spores, and found to be acceptable.
2. It was verified that all spore strips had at least 1.0×10^6 spores per strip.
3. It was verified that the test instruments were inoculated with a spore suspension mixed with 10% sheep blood containing at least 1×10^6 spores per inoculum. It was also verified that the spore recovery method used on the test instruments that could not themselves be submerged in culture broth (e.g. dental handpieces) yielded at least 1×10^6 spores per test instrument.
4. Test data indicated that no spore survivors could be expected at exposure times greater than 5 seconds at the sterilization temperature for the Unwrapped, Heavy Duty Unwrapped and the Wrapped Cycles. Therefore, D-value Determination, Half-Cycle and Total Kill Endpoint Determination could not be performed. Simulated use testing, involving inoculating instruments with the spore suspension mixed with sheep's blood, described above, showed no regular spore survival in test handpieces when processed

in the Wrapped and Heavy Duty Unwrapped Cycles, with loads ranging from a single handpiece to 68 handpieces. Simulated use testing also showed no regular spore survival with solid test instruments in the Unwrapped Cycle, with loads ranging from a single instrument to 86 instruments.

5. The worst case load for the Rubber and Plastics cycle was determined to be the full load of instruments weighing 0.4 kg. The D-value for this load condition was 0.187 minutes. There were no spore strip survivors found after 5.5 minutes of exposure at the sterilization temperature. Simulated use testing, involving inoculating test instruments with a mixture of spore suspension and sheep blood, showed no survivors after 17 minutes of exposure at the sterilization temperature.

The calculated minimum F_0 values are shown in the following table. These do not include the conditioning time at temperatures above 121.1 °C.

Cycle	Nominal Temperature	Time (min.)	F_0 (min.)
Unwrapped Instruments	132 °C	3.5	43.1
Wrapped Instruments	132 °C	6	73.8
Heavy Duty Unwrapped Instruments	132 °C	6	73.8
Rubber and Plastics	121 °C	35	34.2

By using the traditional steam sterilization temperatures and process, and demonstration of the effectiveness and safety of the STAT*IM* 5000, it is concluded that the STAT*IM* 5000 is substantially equivalent to the STAT*IM* Cassette Autoclave, currently on the market in the USA.

Notes:
(a) tested according to BS3970-1990, 1990, Section 12.2.
(b) tested according to ANSI/AAMI ST8-1988 Sections 3.4.1 and 3.4.2.
(c) tested according to ANSI/AAMI ST8-1988 Section 3.4.3.
(d) tested according to ANSI/AAMI ST8-1994 Section 4.4.1.3
(e) tested according to AAMI ST55 (Nov. 1995 Draft) Section 4.4.4.1.