K090265

MAY 15 2009

510(k) Summary

Submitted by:	SciCan Ltd. 1440 Don Mills Road Toronto, Ontario Canada M3B 3P9
Contact Person:	Brenda Murphy - Director of Regulatory Affairs (416) 446-2797
Date of Preparation:	January 30, 2009
Name of Device:	BRAVO series Autoclaves (17, 17V, 21V)
Predicate Device:	M.O.C.O.M. Millennium series Autoclaves 510(k) K050263

Description of Device:

The BRAVO series of Autoclaves are table-top vacuum steam sterilizers designed to process medical and dental instruments to achieve successful sterilization. The units utilize saturated steam at high pressures in order to attain an effective kill of infectious bio-organisms.

BRAVO autoclaves are equipped with either a 17 or 21 litre sterilization chamber and are characterized by an advanced fractionated vacuum system to achieve complete air removal from hollow and porous materials. In addition, they are also equipped with an effective final vacuum drying phase to eliminate any trace of condensation from the finished load.

Instruments are placed onto a sterilization tray which is then inserted into the sterilization chamber and the door is closed. One of the ten preset sterilization cycles is selected and the start button depressed. The unit is microprocessor controlled and therefore fully automatic for the complete sterilizing cycle.

An exclusive steam generation system, combined with an advanced control system, guarantees superior process speed and high stability of the thermodynamic parameters during the entire sterilization process.

The devices offer sterilization programs optimized for the effective and fast sterilization of various instruments and materials used in the medical and dental environments. Depending on the preset cycle chosen, the devices will progress through a series of pulses which consist of one or three vacuum draws followed by pressurization to sterilization temperature in order to remove any air from the sterilization chamber. They will then hold for the preset sterilization time, vent down to atmospheric conditions and begin a heated vacuum drying phase that will run for a predetermined period of time depending on the model as well as the cycle selected. The devices then return to atmospheric conditions so that the door can be opened to remove the processed load.

An example of a standard program is the 134 POROUS/WRAPPED cycle. Once the materials have been arranged on a tray and placed into the sterilization chamber, the door is closed, the program or cycle is selected, and the start key is depressed. This will activate the chamber door locking mechanism and the following sequence will then operate:

- Pre-heating of the steam generator and sterilization chamber;
- Chamber air removal and steam penetration inside the load through a series of vacuum stages and pressure phases;
- Pressure rise-up, with consequent steam temperature increasing up to the preset sterilization conditions (for this example, 134°C /273°F);
- Stabilization of the pressure and temperature conditions inside the sterilization chamber;
- Running of the sterilization process for the preset time (for this example, 4 minutes);
- Chamber pressure decreasing through steam discharge;
- Vacuum drying phase;
- Venting phase through sterile air;
- Chamber pressure leveling up to atmospheric value.
- Release of the door locking mechanism;
- Opening of the door to allow load recovery from the sterilization chamber

Intended use:

The BRAVO Autoclaves are intended to be used in medical and dental practices, hospitals, clinics and other associated facilities to sterilize re-usable medical and dental instruments (including dental handpieces) and medical materials that are heat and moisture resistant and compatible with the steam sterilization process.

Typical users of this system are trained professionals including, but not limited to, dentists, nurses, doctors, infection control and re-processing personnel.

The BRAVO autoclaves are <u>not</u> intended nor recommended for the sterilization of fluids, liquids, or pharmaceutical products.

Technological Characteristics Compared to the Predicate Device:

The intended use, operating principle, general materials of construction and controls are the same for both devices. Both units use saturated steam at high pressures and temperatures to achieve the complete destruction of micro-organisms. The BRAVO autoclaves generate the steam and accomplish air removal using the same method as its predicate, the Millennium autoclaves.

The BRAVO series of Autoclaves offer ten programmed sterilization cycles as described in the above table. The predicate devices, the Millennium autoclaves, have the same ten programmed sterilization cycles. At the end of every sterilization cycle, the BRAVO and Millennium autoclaves automatically begin a heated vacuum dry cycle that will run for a predetermined period of time depending on the model as well as the cycle selected. For both the submitted devices and their predicates, the cycles may be interrupted at any time by pressing and holding the stop button for three seconds. This action terminates the cycle and allows the pressure to return to atmospheric conditions for the chamber door to be manually unlocked and opened only once safe conditions are met. This procedure is the same for both devices. If the cycle is interrupted before the completion of the sterilization portion of the cycle, the message "MANUAL STOP, RESET SYSTEM" will appear on the display and an error code will be printed if a printer is connected.

The sterilization cycles with reference to established times, temperatures and indicated uses for the BRAVO autoclaves are as follows:

TABLE OF AVAILABLE PROGRAMS FOR

BRAVO 17, BRAVO 17V, BRAVO 21V AUTOCLAVES

CYCLE	TEMP.	STER. TIME	DRY TIME	MAX. LOAD (KG)		INTENDED USE
				17/17V	21V	
134 POROUS/WRAPPED	134°C (273°F)	4 min.	16.5 min	1.0 0.75 0.6 3.0 1.5	1.25 1.0 .075 4.0 2.0	Unpackaged porous material Porous material in single package Porous material in double package Solid material / handpieces in single package Solid material / handpieces in double package
121 POROUS/WRAPPED	121°C (250°F)	20 min.	16.5 min	1.0 0.75 0.6 3.0 1.5	1.25 1.0 .075 4.0 2.0	Unpackaged porous material Porous material in single package Porous material in double package Solid material / handpieces in single package Solid material / handpieces in double package
134 HOLLOW/UNWRAP	134°C (273°F)	4 min.	7 min	6.0	7.5	Unpackaged handpieces
121 HOLLOW/UNWRAP	121°C (250°F)	20 min.	7 min	6.0	7.5	Unpackaged handpieces
134 SOLID/WRAPPED	134°C (273°F)	4 min.	16.5 min	3.0	4.0	Solid material in single package
121 SOLID/WRAPPED	121°C (250°F)	20 min.	16.5 min	3.0	4.0	Solid material in single package
134 SOLID/UNWRAP	134°C (273°F)	4 min.	7 min	6.0	7.5	Unpackaged solid material
121 SOLID/UNWRAP	121°C (250°F)	20 min.	7 min	6.0	7.5	Unpackaged solid material
134 EMERGENCY	134°C (273°F)	3 min.	7 min	0.5	0.5	Unpackaged solid material
134°C/121°C CUSTOM	134°C (273°F) OR 121°C (250°F)	>4 min. OR >20 min.	16.5 min OR 7 min	6.0	7.5	Unpackaged solid material (Note: the 134°C/121°C CUSTOM programs have <u>not</u> been validated)
BOWIE-DICK TEST	134°C (273°F)	3.5 min.	7 min			Test pack only (without any other load)
VACUUM	---	---				Empty chamber

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 15 2009

Ms. Brenda Murphy
Director of Regulatory Affairs
SciCan Limited
1440 Don Mills Road
Toronto, Ontario
Canada M3B 3P9

Re: K090265
Trade/Device Name: BRAVO Autoclave
Regulation Number: 21 CFR 880.6880
Regulation Name: Steam Sterilizer
Regulatory Class: II
Product Code: FLE
Dated: April 16, 2009
Received: April 17, 2009

Dear Ms. Murphy:

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 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Susan Runner, D.D.S., MA
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known):

Device Name: BRAVO Autoclave

Indications for Use:

The BRAVO series of Autoclaves are table-top vacuum autoclaves that are intended to be used in medical and dental practices, hospitals, clinics and other associated facilities to sterilize re-usable medical and dental instruments (including dental handpieces) and medical materials that are heat and moisture resistant and compatible with the steam sterilization process.

Typical users of this system are trained professionals including, but not limited to, dentists, nurses, doctors, infection control and re-processing personnel.

The BRAVO series of Autoclaves are not intended nor recommended for the sterilization of fluids, liquids, or pharmaceutical products.

See the following page for the "Table of Available Programs" for the Bravo Autoclave units.

Prescription Use _______ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use X (21 CFR 801 Subpart C)

(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 Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K090205

INDICATIONS FOR USE

TABLE OF AVAILABLE PROGRAMS FOR

BRAVO 17, BRAVO 17V, BRAVO 21V AUTOCLAVES

CYCLE	TEMP.	STER. TIME	DRY TIME	MAX. LOAD (KG)		INTENDED USE
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134 SOLID/WRAPPED	134°C (273°F)	4 min.	16.5 min	3.0	4.0	Solid material in single package
121 SOLID/WRAPPED	121°C (250°F)	20 min.	16.5 min	3.0	4.0	Solid material in single package
134 SOLID/UNWRAP	134°C (273°F)	4 min.	7 min	6.0	7.5	Unpackaged solid material
121 SOLID/UNWRAP	121°C (250°F)	20 min.	7 min	6.0	7.5	Unpackaged solid material
134 EMERGENCY	134°C (273°F)	3 min.	7 min	0.5	0.5	Unpackaged solid material
BOWIE-DICK TEST	134°C (273°F)	3.5 min	7 min			Test pack only (without any other load)
VACUUM	---	---				Empty chamber

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Sheila T. Murphey MD

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K090265