K100887

510(k) Summary of Safety & Effectiveness

Pursuant to CFR 807.92, the following 510(k) Summary is provided:

1. (a)	**Submitter Address:**	George J. Hattub MedicSense, USA 291 Hillside Avenue Somerset, MA 02726 www.medicsense.com
1. (b)	***Manufacturer Address:***	T.A.G. Medical Products Corporation, Ltd. D. N. Ashrat Kibbutz Gaaton 25130, Israel
	Mfg. Phone:	Tel.: 972-3-647-4840
	Contact Person:	Dan Moor
	Date:	August 5, 2010
2.	***Device & Classification Name:***	Sterilization Container, class II device (product code KCT). VersiTomic ™ACL Flexible Reamer System Sterilization Tray
3.	***Predicate Device:***	Paragon Medical Surgical Instrumentation Delivery System (K032119)
4.	***Description:***	The VersiTomic ™ACL Flexible Reamer System Sterilization Tray is a reusable sterilization container system intended to be used to enclose other medical devices that are to be sterilized by a healthcare provider. It is intended to allow sterilization of the enclosed devices and also (when properly wrapped) maintain their sterility device until used. This device is made of durable materials and designed with perforations or slots to allow for steam penetration. It is constructed of machined and formed metal.
5.	***Intended Use:***	The VersiTomic™ ACL Flexible Reamer System Sterilization Tray is indicated to enclose the VersiTomic ACL Flexible Reamer System instruments that are to be sterilized by a health care provider. The Sterilization Tray consists of an interlocking tray and lid, which are both perforated to allow the passage of the sterilizing agent from outside the tray to the devices placed inside. The VersiTomic™ ACL Flexible Reamer System Sterilization tray has been validated with a load that consists of various metallic instruments and implants up to a length of 340 mm and minimum internal diameter of 1.4 mm. The maximum load is 9.6 kg (21.1 lb) which is distributed equally within the tray.

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The VersiTomic™ ACL Flexible Reamer System Sterilization Tray has been validated for steam sterilization using the following parameters:

Gravity-Displacement Steam Sterilization

- Sterilizer Type: Gravity
- Minimum Temperature: 132°C (270°F)
- Minimum Exposure Time: 10 minutes
- Minimum Dry Time: 40 minutes

Pre-Vacuum Steam Sterilization

- Sterilizer Type: Pre-Vacuum
- Minimum Temperature: 132°C (270°F)
- Minimum Exposure Time: 4 minutes
- Minimum Dry Time: 15 minutes

6. ***Comparison of Technological Characteristics:***

With respect to its indication for use, the VersiTomic™ ACL Flexible Reamer System Sterilization Tray is substantially equivalent to its predicate device in that it intended for the same clinical purpose. With respect to technology, the design is similar as confirmed by comparison, and the performance is the same as verified by validation. Based upon this, T.A.G. Medical Products Corporation, Ltd. believes that its device is safe and effective because it performs the same function in the same manner.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

T.A.G. Medical Products
C/O Mr. George J. Hattub
MedicSense, USA
291 Hillside Avenue
Somerset, Massachusetts 02726

AUG 09 2010

Re: K100887
Trade/Device Name: VersiTomic ™ ACL Flexible Reamer System Sterilization Tray
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: II
Product Code: KCT
Dated: July 19, 2010
Received: July 29, 2010

Dear Mr Hattub:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

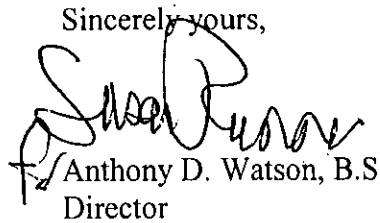
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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 (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Anthony D. Watson, B.S., M.S., M.B.A.
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

AUG 09 2010

510(k) Number (if known): K100887

Device Name: VersiTomic™ ACL Flexible Reamer System Sterilization Tray

Indications For Use: The VersiTomic™ ACL Flexible Reamer System Sterilization Tray is indicated to enclose the VersiTomic ACL Flexible Reamer System instruments that are to be sterilized by a health care provider.
The Sterilization Tray consists of an interlocking tray and lid, which are both perforated to allow the passage of the sterilizing agent from outside the tray to the devices placed inside.

The VersiTomic™ ACL Flexible Reamer System Sterilization tray has been validated with a load that consists of various metallic instruments and implants
up to a length of 340 mm and minimum internal diameter of 1.4 mm. The maximum load is 9.6 kg (21.1 lb) which is distributed equally within the tray.

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Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 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

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