K053464

JUN - 6 2006

510(k) Summary of Safety and Effectiveness

510(k) Summary	This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR § 807.92 and the Safe Medical Device Act of 1990.
Submitter	ConMed Integrated Systems, Canada, ULC 3755 Boul. Matte, Suite F Brossard, Quebec, Canada J4Y 2P4
Contact Person	Michael T. Taggart Vice President, Regulatory Affairs and Quality Management ConMed Linvatec Phone: (727) 399-5334 Fax: (727) 399-5264 E-mail: mtaggart@linvatec.com
Device Trade Name	SM40SE
Device Common Name	Space Management Systems with Integrated Smoke Plume Evacuator
Device Classification Names	Surgical Exhaust Apparatus
Device Classification	Device Class: II Product Code: FYD Classification Panel: General & Plastic Surgery Regulation Number: 878.5070

Predicate / Legally Marketed Devices

510(k) Number	Device	Manufacturer
K955750	Teletom	Berchtold Holding GMBH
K924732	Plumesafe Whisper 602™ Smoke Evacuation System	Buffalo Filter Co., Inc.

Device Description	The SM40SE is a space management custom configured consoles into which a variety of medical devices are integrated including a surgical smoke evacuator. These SM40SE consoles are suspended from articulated ceiling pendant in general operating rooms, minimally invasive surgery suites and post-anaesthesia care units.
Intended Use	The intended use for the SM40SE console is to position and manage devices such as medical gas, high and low voltage electrical, communication and accessories such as equipment shelves, drawers, IV poles and smoke evacuation units. The smoke plume evacuator integrated into the SM40SE is intended for the evacuation and filtration of smoke plume and odor generated during laser or electrosurgery.
Substantial Equivalence	The SM40ES is substantially equivalent in design and intended use and the predicate devices identified below. *1. PlumeSafe Whisper 602™ (K924732)* The use of this device is for the evacuation of smoke fumes and odor generated during laser and electrosurgery. The device draws smoke plume from the surgical site by means of a vacuum hose into a filter. The smoke plume is then filtered through the disposable filtration device and exhausted through the vacuum/blower into the surrounding area. *2. Teletom (K955750)* Teletom(tm) Power Boom is intended to provide multiple platforms to support and position equipment and to provide delivery systems for electrical power and medical gases. The smoke plume evacuator (Televac®) integrated into the Teletom™ Power Boom intended for the evacuation and filtration of smoke plume and odor generated during laser or electrosurgery.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 6 2006

ConMed Linvatec.
% Mr. Michael Taggart
VP, Quality Management and Regulatory
Affairs
11311 Concept Boulevard
Largo, Maryland 33773-4908

Re: K053464
Trade/Device Name: SM40SE
Regulation Number: 21 CFR 878.5070
Regulation Name: Air-handling apparatus for a surgical operating room
Regulation Class: II
Product Code: FYD
Dated: April 21, 2006
Received: April 24, 2006

Dear Mr. Taggart:

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 such 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); 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.
This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

CONFIDENTIAL

INDICATIONS FOR USE

510(k) Number (if known): K053464

Device Name:

SM40SE

Indications for Use

The intended use for the SM40SE console is to position and manage devices such as medical gas, high and low voltage electrical, communication and accessories such as equipment shelves, drawers, IV poles and smoke evacuation units.

The smoke plume evacuator integrated into the SM40SE is intended for the evacuation and filtration of smoke plume and odor generated during laser or electrosurgery.

Prescription Use X
(Part 21 CFR 801 subpart D)

OR

Over-the-Counter Use ___
(Part 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 General, Restorative, and Neurological Devices

510(k) Number K053464