DEC 2 1 2012

510(k) Summary of Safety and Effectiveness

ConMed® DetachaTip® III Multi-Use Laparoscopic Instrument

In accordance with the requirements of the Safe Medical Device Act of 1990 and 21CFR 807.92, ConMed Corporation is hereby submitting the 510(k) Summary of Safety and Effectiveness for 510(k) number **K123260** as of December 14, 2012.

A. Submitter

ConMed Corporation
525 French Road
Utica, NY 13502

Establishment Registration: 1320894

B. Company Contact

Lisa Anderson
Manager, Regulatory Affairs
T: (315) 624-3371
F: (315) 624-3225

C. Device Name

Proprietary Name:	DetachaTip® III
Common Name:	Multi Use Laparoscopic Instruments
Classification Name:	Electrosurgical, Cutting & Coagulation & Accessories
Regulation Number:	878.4400
Product Code:	GEI
Regulatory Class:	II
Panel:	General and Plastic Surgery

D. Predicate Devices

Device Name:	DetachaTip Surgical Instruments
Company Name:	ConMed Corporation via acquisition of Imagyn Medical Technologies / Microsurge, Inc.
510(k):	K924283

Device Name:	Unimax Laparoscopic Instrument
Company Name:	Unimax Medical Systems, Inc.
510(k):	K103508

Device Name:	Laparoscopic Dissector
Company Name:	Applied Medical Resources Corporation
510(k):	K103282
Device Name:	Laparoscopic Switch-Blade Scissors
Company Name:	Snowden Pencer, Inc.
510(k):	K030890

E. Device Description

The DetachaTip® III Multi Use Laparoscopic Instrument family comprises a series of sterile, multi-use laparoscopic scissors, graspers and dissectors designed to be used in conjunction with an appropriately sized cannula. All the instruments provide monopolar electrosurgical capability via a standard 4mm monopolar post. A single handle design accommodates 33cm and 43cm instrument shafts. Instrument shafts are available in a variety of blade or jaw configurations.

For graspers and dissectors, a lever on the handle allows the user to activate the ratcheting feature in a fixed ON/OFF position or an intermittent position. The ratcheting mode changes from intermittent to "OFF" once the user releases the lever. The ratcheting feature is intended for use with the grasper and dissector shafts only. The design of the scissors instrument shaft does not allow for ratcheting of those instruments.

A rotator knob on the instrument shaft allows for 360°axial rotation of the shaft and tip. The devices are designed with a Luer port located on the rotator knob that allows for flushing of the central shaft prior to steam sterilization.

F. Intended Use / Indications for Use

The DetachaTip® III Multi Use Instruments are intended for use in a variety of laparoscopic procedures to transect, dissect, grasp, and coagulate tissue.

G. Non-clinical Performance Testing

Non-clinical bench and simulated use testing demonstrated the DetachaTip® III Multi Use Laparoscopic instruments are substantially equivalent to Detacha-Tip Surgical Instruments with regard to intended use, materials, technology, and performance. Design verification testing demonstrates the devices comply with the applicable sections of AAMI/ANSI ES60601-1:2005 and IEC 60601-2-2:2009. Material analysis demonstrates the DetachaTip III materials comply with the requirements of ISO 10993-1:2009.

H. Substantial Equivalence

The differences between the predicates and the modified design do not raise any new risks of safety or efficacy. Supporting information per this premarket submission confirms that the ConMed DetachaTip® III Multi Use Laparoscopic instruments are safe and effective for their intended use and are substantially equivalent to the Detacha-Tip Surgical Instruments, the Unimax Laparoscopic Instruments, the Applied Medical Laparoscopic Dissector and the Snowden Pencer Switch-Blade Scissors.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Conmed Corporation
% Ms. Lisa Anderson
Manager, Regulatory Affairs
525 French Road
Utica, New York 13502

December 21, 2012

Re: K123260
Trade/Device Name: ConMed Detacha Tip® III Multi-Use Laparoscopic Instruments
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: October 17, 2012
Received: October 22, 2012

Dear Ms. Anderson:

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,

Peter D. Rumm -S

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K123260

Device Name: ConMed DetachaTip® III Multi-Use Laparoscopic Instruments

Indications for Use:

The DetachaTip® III Multi Use Instruments are intended for use in a variety of laparoscopic procedures to transect, dissect, grasp, and coagulate tissue.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Dwight Yen
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(Division Sign-Off)

Division of Surgical Devices

510(k) Number ____K123260_____