ConMed Linvatec
11311 Concept Boulevard • Largo, FL 33773-4908 • 727-392-6464 • www.linvatec.com

510(k) Summary
ConMed Linvatec Anodized Aluminum Sterilization Trays

In accordance with the requirements of the Safe Medical Device Act of 1990 and 21 CFR 807.92, ConMed Linvatec is hereby submitting a 510(k) Summary of Safety and Effectiveness for 510(k) Number K090560

JUN 29 2009

Submitter	ConMed Linvatec 11311 Concept Blvd. Largo, Florida 33773-4908 Establishment Registration Number 1017294
Company Contact	Rebecca Roberts, RAC Regulatory Affairs Specialist Telephone 727-399-5564 Fax 727-399-5264
Family Name	ConMed Linvatec Anodized Aluminum Sterilization Trays
Device Name	Hip Arthroscopy Master Tray, ST7900 PowerPro Small System Sterilization Case, PRO5095 Hall Sterilization Tray, PRO6000
Classification Name	Sterilization Wrap Containers, Cassettes and other Accessories
& Regulation number	21 CFR 880.6850 Infection Control Devices Branch
Proposed Class/Device	Class II
Product Code	KCT
Predicate Device	ConMed Linvatec Microfracture Instrument Sterilization Tray (MFX-TRAY), K080531

Device Description

ConMed Linvatec Anodized Aluminum Sterilization Trays are constructed of metal with perforations to facilitate sterilant penetration, evacuation and drying. These trays are designed to fit any standard autoclave and are manufactured from durable, biocompatible materials that are corrosion resistant and compatible with the environment of repeated steam sterilization. Since the trays are perforated, an FDA cleared sterilization wrap must be used to maintain sterility of

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the contents. Although these trays are reusable they will not be serviced or repaired.

ConMed Linvatec Anodized Aluminum Sterilization Trays are available under various trade names and in various sizes and tray configurations. Interior structures of the trays have the ability to separately hold each individual instrument during the entire duration they are in contact with the tray.

Intended Use:

ConMed Linvatec Anodized Aluminum Sterilization Trays is a family of containment devices for medical device sterilization.

The Hip Arthroscopy Master Tray is intended for use only with the following instruments and/or other instruments of similar type and size:

REF	Description	REF	Description
S210GSP	Grasping Forceps, 210mm	25.50014EL	Extended Length Liberator Knife
S210SRF	Suture Retrieval Forceps, 210mm	25.50016EL	Extended Length Liberator Rasp
S210MSC	Micro-scissors, 210mm	C6105EL	Extended Length Crochet Hook
S210AFU	Aggressor Forcep, 15° Up, 210mm	8748EL	Extended Length Knot Pusher
S210AFL	Aggressor Forcep,15° Left, 210mm	9837	Extended Length Hip Obturator
S210AFR	Aggressor Forcep, 15° Right, 210mm	A55-012-022	Bio Mini Revo® Blunt, Obturator
S210RFR	Rotary Forcep Right, 210mm	A55-012-023	Bio Mini Revo Trocar, Obturator
S210RGF	Retrograde Forceps, 210mm	A55-012-113	Bio Mini Revo Drill Bit
S210RFL	Rotary Forcep Left, 210mm	A55-012-130	Bio Mini Revo Bone Punch, 3mm
C6171EL	Extended Length Drill Guide Fishmouth	A55-012-120	Bio Mini Revo Tap, 3mm
C6172EL	Extended Length Drill Guide Serrated	GU1009EL	Extended Length Katana
SC7900	Slotted Cannula, 6.7mm	GU1004EL	Extended Length Raven, Straight
SC6900	Slotted Cannula, 5.0mm	21.1001EL	XO Button Depth Probe

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Sterilize the Hip Arthroscopy Master Tray using the following parameters:

Method	Cycle	Minimum Temperature	Minimum Exposure	Minimum Dry Cycle
Steam (wrapped)	Pre-vacuum	270°F(132°C)	4 minutes	20 minutes
Steam (wrapped)	Gravity	270°F(132°C)	15 minutes	25 minutes

The PowerPro® Small System Sterilization Case (PRO5095) and the Hall® Sterilization Tray (PRO6000) are designed to hold a variety of powered ConMed Linvatec handpieces as well as attachments and/or accessories that may be used with the powered handpieces.

Cannulated handpieces or attachments with an internal diameter not less than 0.031 inches (0.079cm) and a cannulated length no greater than 5.75 inches (14.61cm) and/or handpiece accessories such as pneumatic air supply hoses with a lumen not less than 0.187 inches (0.475 cm) in diameter and a cannulated length no greater than 15 feet (4.6 m) may be sterilized in this tray along with other non-cannulated, non-porous instruments.

Sterilize the PowerPro® Small System Sterilization Case (PRO5095) and the Hall® Sterilization Tray (PRO6000) using the following parameters.

Method	Cycle	Minimum Temperature	Minimum Exposure	Minimum Dry Cycle
Steam (wrapped)	Pre-vacuum	270°F(132°C)	4 minutes	25 minutes
Steam (wrapped)	Gravity	270°F(132°C)	15 minutes	35 minutes

CAUTION: Testing demonstrates that a minimum dry time of 35 minutes is required to prevent wet packs when using the gravity cycle.

Substantial Equivalence

The proposed and the predicate devices are substantially equivalent in design, materials and intended use. The proposed devices and the predicate devices are containment devices for sterilization of reusable medical devices using steam sterilization. The proposed devices present no new issues of safety and efficacy.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 29 2009

Ms. Robecca Roberts
Regulatory Affairs Specialist
ConMed Linvatec
11311 Concept Boulevard
Largo, Florida 33773-4908

Re: K090560
Trade/Device Name: Hip Arthroscopy Master Tray (ST7900) PowerPro® Small System Sterilization Case, PRO5095, Hall Sterilization Tray, PRO6000
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: II
Product Code: KCT
Dated: June 16, 2009
Received: June 17, 2009

Dear Ms. Roberts:

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 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/cdrh/mdr/ 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Susan Runner

Susan Runner, D.D.S., M.A.
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): K090560/S001

Family Name: ConMed Linvatec Anodized Aluminum Sterilization Trays

Trade Name: PowerPro® Small System Sterilization Case, PRO5095
Hall® Sterilization Tray, PRO6000

Indications for Use:
ConMed Linvatec Anodized Aluminum Sterilization Trays is a family of containment devices for medical device sterilization.

The PowerPro® Small System Sterilization Case (PRO5095) and the Hall® Sterilization Tray (PRO6000) are designed to hold a variety of powered ConMed Linvatec handpieces as well as attachments and/or accessories that may be used with the powered handpieces.

Cannulated handpieces or attachments with an internal diameter not less than 0.031 inches (0.079cm) and a cannulated length no greater than 5.75 inches (14.61cm) and/or handpiece accessories such as pneumatic air supply hoses with a lumen not less than 0.187 inches (0.475 cm) in diameter and a cannulated length no greater than 15 feet (4.6 m) may be sterilized in this tray along with other non-cannulated, non-porous instruments.

Sterilize the PowerPro® Small System Sterilization Case (PRO5095) and the Hall® Sterilization Tray (PRO6000) using the following parameters.

Method	Cycle	Minimum Temperature	Minimum Exposure	Minimum Dry Cycle
Steam (wrapped)	Pre-vacuum	270°F(132°C)	4 minutes	25 minutes
Steam (wrapped)	Gravity	270°F(132°C)	15 minutes	35 minutes

CAUTION: Testing demonstrates that a minimum dry time of 35 minutes is required to prevent wet packs when using the gravity cycle.

Prescription Use_____ AND/OR Over-the-Counter Use ___X___
(Part 21 CFR 801 Subpart D) (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)

Shirle A. Murphy

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

510(k) Number: K090560

INDICATIONS FOR USE

510(k) Number (if known): K090560

Family Name: ConMed Linvatec Anodized Aluminum Sterilization Trays

Trade Name: Hip Arthroscopy Master Tray (ST7900)

Indications for Use:

ConMed Linvatec Anodized Aluminum Sterilization Trays is a family of containment devices for medical device sterilization.

The Hip Arthroscopy Master Tray is intended for use only with the following instruments:

REF	Description	REF	Description
S210GSP	Grasping Forceps	25.50014EL	EL Liberator
S210SRF	Suture Retrieval	25.50016EL	EL Rasp
S210MSC	Micro-scissors	C6105EL	EL Crochet Hook
S210AFU	Aggressor Forcep Up	8748EL	EL Knot Pusher
S210AFL	Aggressor Forcep Left	9837	EL Hip Obturator
S210AFR	Aggressor Forcep Right	A55-012-022	BMR Obturator, Blunt
S210RFR	Rotary Forcep Right	A55-012-023	BMR Obturator, Trocar
S210RGF	Retrograde Forceps	A55-012-113	BMR Drill Bit
S210RFL	Rotary Forcep Left	A55-012-130	BMR Bone Punch
C6171EL	EL Drill Guide Fishmouth	A55-012-120	BMR Tap
C6172EL	EL Drill Guide Serrated	GU1009EL	EL Katana
SC7900	Slotted Hip Cannula, 6.7mm	GU1004EL	EL Raven, Straight
SC6900	Slotted Hip Cannula, 5.0mm	21.1001EL	EL Probe

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

510(k) Number: K090560