APR 1 0 2006

April 6, 2006

SUMMARY OF SAFETY AND EFFECTIVENESS

In accordance with the requirements of the Safe Medical Device Act of 1990 and 21 CFR 807.92, Linvatec Corporation is hereby submitting the Special 510(k) Summary of Safety and Effectiveness for the MicroPower Hand Piece: Oral Max High Speed Drill.

A. Submitter

ConMed Linvatec
11311 Concept Boulevard
Largo, Florida 33773-4908
Registration Number: 1017294

B. Company Contact

Elizabeth Paul
Manager, Regulatory Affairs
(727) 399-5234 Telephone
(727) 399-5264 FAX

C. Device Name

Trade Name:	MicroPower Hand Piece: Oral Max High Speed Drill
Common Name:	Surgical Drill System
Classification Names:	872.4120 – Bone cutting instrument and accessories
Proposed Class/Device:	Class II
Product Code:	DZI

D. Predicate/Legally Marketed Devices

K971059 – Universal Drive System

E. Device Description

The *MicroPower Hand Piece: Oral Max High Speed Drill* device description MicroChoice product line cleared is identical to the original submission except for the modifications which have been detailed in Section 9 of this submission. These modifications do not affect the device's intended use, fundamental scientific technology or performance specifications so that any new issues regarding safety and effectiveness are raised.

The MicroPower hand pieces are electric and based upon the existing Microchoice hand piece platform cleared under K971059. Both are pencil grip handhelds that are used in conjunction with the Advantage®, E9000® and PowerPro® controllers. A chord connects the hand pieces to the controllers that supply power to the device. The hand pieces have a lever that is used to actuate the device. The drills use a wide variety of bur guards, attachments, drill bits and burs. The saws use a wide variety of blades. The MicroPower drill and saws will use the same burs and blades that the current Microchoice hand pieces use.

Intended Use

The MicroPower Hand Piece: Oral Max High Speed Drill functions as a powered instrument system consisting of drills, saws and associated handpieces to perform cutting of soft tissue and bone. The field of application has changed slightly from the predicate device, in that the Oral Max High Speed Drill only includes oral/maxillofacial procedures.

F. Substantial Equivalence

The *MicroPower Hand Piece: Oral Max High Speed Drill* is substantially equivalent in indication for use, scientific technology and design to the MicroChoice Universal Drive System. The Universal Drive System was cleared by FDA under 510(k) K971059. The changes made to the Universal Drive System have been tested to assure that the proposed modifications do not raise any new issues regarding safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 10 2006

ConMed Linvatec Corporation
c/o Ms. Elizabeth M. Paul
Manager, Regulatory Affairs
11311 Concept Boulevard
Largo, Florida 33773-4908

Re: K060270
Trade/Device Name: MicroPower Hand Piece: OralMax High Speed Drill
Regulation Number: 21 CFR 872.4120
Regulation Name: Bone cutting instrument and accessories
Regulatory Class: II
Product Code: DZI
Dated: March 16, 2006
Received: March 17, 2006

Dear Ms. Paul:

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

Indications for Use

510(k) Number (if known): K060270

Device Name: MicroPower Hand Piece: OralMax High Speed Drill

Indications for Use:

The MicroPower Hand Piece: OralMax High Speed Drill, functions as a powered instrument system consisting of drills, saws and associated handpieces to perform cutting of soft tissue and bone. The field of application includes only oral/maxillofacial.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(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)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K060270