K032607

NOV 1 0 2003

PROPRIETARY INFORMATION – LINVATEC CORPORATION

August 21, 2003

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 510(k) Summary of Safety and Effectiveness for the PowerPro® Pneumatic System, 510(k) Number _____.

A. Submitter

Linvatec Corporation
11311 Concept Boulevard
Largo, Florida 33773-4908

B. Company Contact

Laura D. Krejci, RAC
Manager, Regulatory Affairs
(727) 399-5234 Telephone
(727) 399-5264 FAX

C. Device Name

Trade Name: PowerPro® Pneumatic System

Common Name: Powered surgical instrument and accessories/attachments

Classification Names:
Surgical instrument motors and accessories/attachments 878.4820
Bone cutting instrument and accessories 872.4120
Pneumatic cranial drill motor 882.4370

Proposed Class: II
Product Codes: GET, DZI, HBB, KFK

D. Predicate/Legally Marketed Devices

PowerPro® Electric System Linvatec Corporation	510(k) #K981269
Hall® Surgical Series 4® System Linvatec Corporation	510(k) #K832187
Midas Rex Legend System Medtronic Midas Rex	510(k) #K020069

E. Device Description

The PowerPro® Pneumatic System is a pneumatically powered system consisting of handpieces and attachments for cutting bone in various large and small bone procedures. The PowerPro® Pneumatic handpieces are pistol-grip handpieces. The handpieces utilize various attachments, such as blades, burs, drills and routers that are also used with Linvatec's PowerPro® Electric and Battery Systems.

F. Intended Use

The PowerPro® Pneumatic System consists of handpieces and attachments intended to be used for cutting, drilling, tapping, reaming, and driving screws and pins in large and small bone during orthopedic, spinal, neurosurgical, medial sternotomy, and oral and maxillofacial procedures.

G. Substantial Equivalence

The PowerPro® Pneumatic System is substantially equivalent in design, function and intended use to the predicate devices named above. The PowerPro® Pneumatic System does not raise any new safety or effectiveness issues when compared to these similar devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 1 0 2003

Ms. Laura D. Krejci, RAC
Manager, Regulatory Affairs
Linvatec Corporation
11311 Concept Boulevard
Largo, Florida 33773

Re: K032607
Trade/Device Name: PowerPro® Pneumatic System
Regulation Number: 21 CFR 872.4120, 878.4820, 882.4370
Regulation Name: Bone cutting instrument and accessories, Surgical instrument motors and Accessories/attachments, Pneumatic cranial drill motor
Regulatory Class: II
Product Code: DZI, HSZ, HBB
Dated: August 21, 2003
Received: August 25, 2003

Dear Ms. Krejci:

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 (301) 594-4659. 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,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

August 21, 2003

510(k) Number (if known): K032607

Device Name: PowerPro® Pneumatic System

Indications for Use:

The PowerPro® Pneumatic System consists of handpieces and attachments intended to be used for cutting, drilling, tapping, reaming, and driving screws and pins in large and small bone during orthopedic, spinal, neurosurgical, medial sternotomy, and oral and maxillofacial procedures.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use___ OR Over-the-Counter Use___
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Miriam C. Provost

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

510(k) Number K032607