



JUL 15 1999

June 28, 1999

510(k) 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 E9000 System, 510(k) Number K990524.

A. Submitter

Linvatec Corporation
11311 Concept Boulevard
Largo, Florida 33773-4908

B. Company Contact

Laura Seneff
Manager, Regulatory Affairs

C. Device Name

Trade Name:	:	E9000 System
Common Name	:	Integrated Drive/Pump System
Classification Name	:	Surgical, ENT (electric or pneumatic), including handpiece - 874.4250 Electric cranial drill motor - 882.4360 Infusion Pump - 880.5725 Surgical instrument motors and accessories/attachments - 878.4820 Bone cutting instrument and accessories - 872.4120

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D. Predicate/Legally Marketed Devices

Integrated Drive/Pump System (Hall E9000 System)
Linvatec Corporation

Universal Drive System (MicroChoice System)
Linvatec Corporation

Hall Sternum Saw
Linvatec/Hall Surgical

E. Device Description

The E9000 System is a combination drive system and irrigation console, which consists of an AC powered drive/pump console, a power cord, a footswitch, a sterilizable handpiece cord, various motorized handpieces, associated shavers, blades, burs, bur guards, routers, irrigation tubing sets, and bur tips.

F. Intended Use

The E9000 System functions as a powered instrument system consisting of drills, saws, and associated handpieces to perform cutting of soft tissue and bone. The fields of application include: Orthopedic, Arthroscopic, Otolaryngological, Oral/Maxillofacial, Hand, Foot, Neuro, Medial Sternotomy, Spinal and Plastic/Reconstructive surgical procedures.

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G. Substantial Equivalence

The E9000 System is substantially equivalent in design, function and intended use to the Hall E9000 Integrated Drive/Pump System (Linvatec Corporation), the MicroChoice Universal Drive System (Linvatec Corporation) and the Hall Sternum Saw (Linvatec/Hall Surgical).

Testing has been done to prove safety and effectiveness of the devices.

The similarities/dissimilarities to the predicates are shown in the attached table.

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CHART OF SIMILARITIES AND DISSIMILARITIES

DEVICE NAME	E9000 SYSTEM	HEALTH E9000 SYSTEM	MICROCHOICE UNIVERSAL DRIVE SYSTEM	HEALTH SUPERNUMERALS
INTENDED USE	Resection of tissue and bone during arthroscopic, orthopedic, otolaryngological, oral/maxillofacial, hand, foot, neurological, spinal, plastic/reconstructive and medial sternotomy surgical procedures.	Resection of soft tissue and bone during orthopedic, otolaryngological, neurological and spinal surgical procedures.	Resection of soft tissue and bone cutting during arthroscopic, orthopedic, oral/maxillofacial, otolaryngological, hand, foot, neurological and plastic/reconstructive surgical procedures.	Cutting of bone beginning the suprasternal notch or the xiphoid process during a medial sternotomy.
510(K) NUMBER	K990254	K981636 & K981637	K971059	K862474
ACCESSORIES	Blades, Burs, Routers, Attachments, Bur Guards, Bur Tips, Irrigation Tubing Sets, Foot Control, Shaver Adapter, Universal Cord	Blades, Burs, Routers, Attachments, Bur Guards, Bur Tips, Irrigation Tubing Sets, Foot Control, Shaver Adapter, Universal Cord	Blades, Burs, Attachments, Foot Control	Blades, Battery Pack
DEVICE COMPONENT	Drive/Pump Console, Cranial Perforator, High Speed Drill, Medium Speed Drill, Reciprocating Saw, Oscillating Saw, Low Speed Drill, Modular Handpiece, Wiredriver, Large Shaver Handpiece, Full-Function Handpiece, Small Shaver Handpiece, Micro Handpiece	Drive/Pump Console, High Speed Shaver Handpiece, High Speed Drill, Cranial Perforator, Micro Handpiece, Sagittal Saw	Universal Drive Console, Micro Joint Handpiece, Standard Handpiece, Full-Function Handpiece, Low Speed Drill, Medium Speed Drill, High Speed Drill, Oscillating Saw, Sagittal Saw, Reciprocating Saw, Wiredriver	Handpiece
MATERIAL	Aluminum, Stainless Steel	Aluminum, Stainless Steel	Aluminum, Stainless Steel	Stainless Steel



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 15 1999

Ms. Laura Seneff
Manager Regulatory Affairs
Linvatec Corporation
11311 Concept Boulevard
Largo, Florida 33773-4908

Re: K990524
Trade Name: E9000 System
Regulatory Class: II
Product Code: HRX
Dated: May 27, 1999
Received: May 28, 1999

Dear Ms. Seneff:

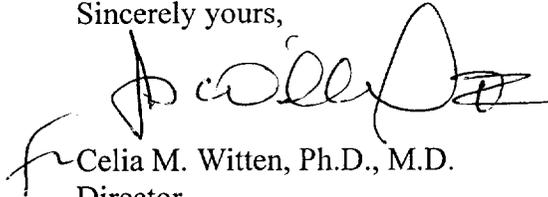
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,

A handwritten signature in black ink, appearing to read "Celia M. Witten". The signature is fluid and cursive, with a large loop at the end.

Celia M. Witten, Ph.D., M.D.

Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

June 28, 1999

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510(k) Number (if known): K990524

Device Name: E9000 System

Indications for Use:

The E9000 System functions as a powered instrument system consisting of drills, saws, and associated handpieces to perform cutting of soft tissue and bone. The fields of application include: Orthopedic, Arthroscopic, Otolaryngological, Oral/Maxillofacial, Hand, Foot, Neuro, Medial Sternotomy, Spinal and Plastic/Reconstructive surgical procedures.

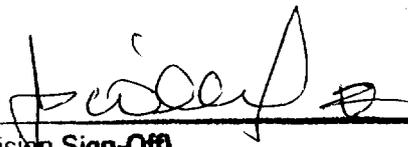
(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

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)



(Division Sign-Off)
Division of **General Restorative Devices**
510(k) Number K990524