

AUG 20 1998



11311 Concept Boulevard Largo, Florida 33773-4908 813 392-6464

981636

May 7, 1998

**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 Integrated Drive/Pump System, 510(k) Number 981636.

**A. Submitter**

Linvatec Corporation  
11311 Concept Boulevard  
Largo, Florida 33773-4908

**B. Company Contact**

Carol A. Weideman, Ph.D.  
Director, Compliance and Regulatory Affairs

**C. Device Name**

Trade Name: : Integrated Drive/Pump System  
Common Name : Integrated Drive/Pump System  
Classification Names : 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

**D. Predicate/Legally Marketed Devices**

Universal Drive System  
Linvatec Corporation

Hall® Irrigation System  
Linvatec Corporation

Summary of Safety and Effectiveness  
Integrated Drive/Pump System  
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#### G. Substantial Equivalence

The Integrated Drive/Pump System is substantially equivalent in design, function and intended use to the Universal Drive System (Linvatec Corporation), Hall® Irrigation System (Linvatec Corporation), TPS Total Performance System (Stryker Endoscopy), and Hummer 2® (Stryker Endoscopy).

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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Integrated Drive/Pump System  
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**D. Predicate/Legally Marketed Devices (Con't)**

TPS Total Performance System  
Stryker Endoscopy

Hummer 2®  
Stryker Endoscopy

**E. Device Description**

The Integrated Drive/Pump System is a combination of the Linvatec Universal Drive System and Hall® Irrigation System with the addition of three new handpieces used in Otolaryngology, Neurological Surgical, Orthopedic, and Spinal procedures.

The Integrated Drive/Pump System consists of an AC powered drive/pump console, a sterilizable handpiece cord, a high speed handpiece, high speed drill, cranial perforator, various blades, burs, bur guards, irrigation tubing sets, shaver adapter, and a footswitch.

**F. Intended Use**

The Integrated Drive/Pump System functions as a powered instrument system consisting of blades, burs, bur guards, associated handpieces, drive/pump console, footswitch, shaver adapter, and irrigation tubing sets to perform resection of soft tissue and bone. The fields of application include: Otolaryngology, Neurological Surgical, Orthopedic, and Spinal surgical procedures.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

AUG 20 1998

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Carol A. Weideman, Ph.D.  
Director, Compliance and Regulatory Affairs  
Linvatec Corporation  
11311 Concept Boulevard  
Largo, Florida 33773-4908

Re: K981636  
Trade Name: Integrated Drive/Pump System  
Regulatory Class: II  
Product Code: HRX  
Dated: July 28, 1998  
Received: July 29, 1998

Dear Dr. Weideman:

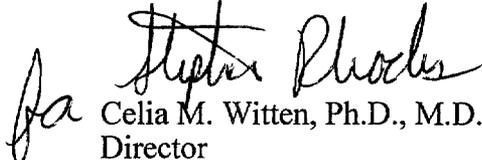
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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) 594-4595. 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,

The signature is written in cursive and appears to read "Celia M. Witten". To the left of the signature is a handwritten mark that looks like "ca".  
Celia M. Witten, Ph.D., M.D.  
Director  
Division of General and  
Restorative Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health



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Device Name: Integrated Drive/Pump System

Indications for Use:

The Integrated Drive/Pump System functions as a powered instrument system consisting of blades, burs, bur guards, associated handpieces, drive/pump console, footswitch, shaver adapter, and irrigation tubing sets to perform resection of soft tissue and bone. The fields of application include: Otolaryngology, Neurological Surgical, Orthopedic, and Spinal 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 X OR Over-the-Counter Use \_\_\_\_\_

(Per 21 CFR 801.109)

Stephen Rhoads  
(Division Sign-Off)  
Division of General Restorative Devices  
510(k) Number K981636

(Optional Format 1-2-96)