JUL 20 1998

K981637

July 13, 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 K981637.

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

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 surgical 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 field of application is Otolaryngology surgical procedures.

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.

CHART OF SIMILARITIES

Company	Device Name	Intended Use	S
NEW PRODUCT Linvatec	Integrated Drive/Pump System	Resection of soft tissue and bone during Otolaryngology surgical procedures.	S H V P
PREDICATE Linvatec 510(k) #K971059	Universal Drive System	To perform cutting of soft tissue and bone in the applications of : Arthroscopic/Orthopedic, Otolaryngological and Reconstructive Surgery	S s b S
PREDICATE Linvatec 510(k) #K961192 #K852143	Hall® Irrigation System	General, Reconstructive surgery, and Otolaryngological	S i
PREDICATE Stryker Endoscopy 510(k) #K943569 #K943589	TPS Total Performance System	Resection of soft tissue and bone in the applications of: Spinal, Foot and Ankle, Plastics, ENT, and Neuro	S I

AND DISSIMILARITIES

ystem Components and Design
ystem consists of: Drive/Pump Console, High Speed Handpiece, igh Speed Drill, Cranial Perforator, Irrigation Tubing Sets, arious Blades, Burs, Bur Guards, Footswitch, Shaver Adapter, ower Cord, and Handpiece Cord.
ystem consists of: Universal Controller, Foot Control, "Apex tyle" Handpieces and associated attachments, blades, and urrs. haver blades & burrs: length 75-200mm, diameter 2.0-6.0mm.
ystem consists of: Irrigation console, irrigation sensor, rrigation tubing set, and irrigation attachment clips
ystem consists of: Drive Console, Handpieces, Footswitch, rills, Saws, Dura Guards, and Angled Attachments.

CHART OF SIMILARITIES

Company	Device Name	Intended Use	S
PREDICATE Stryker Endoscopy 510(k) #K952681	Hummer 2®	Resection of soft tissue and bone in the applications of: Head & Neck and ENT	S cu

; AND DISSIMILARITIES

ystem Components and Design
ystem consists of: Drive/Pump Console, Handpiece, footswitch, ıtters, and Irrigation Tubing Set.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 20 1998

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

Re: K981637
Integrated Drive/Pump System for Otolaryngology
Dated: May 7, 1998
Received: May 8, 1998
Regulatory class: II
21 CFR 874.4250/Procode: 77 ERL

Dear Dr. Weidman:

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 requirements, 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) 594-4613. 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/dsma/dsmamain.html".

Sincerely yours,

Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Linvatec

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510(k) Number (if known): K981637

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 field of application is Otolaryngology 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)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K981637

(Optional Format 1-2-96)