K981269

JUN 24 1998

Linvatec

11311 Concept Boulevard Largo, Florida 33773 813 399-5334 Fax 813 399-5264

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

April 6, 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 Universal Drive System, 510(k) Number _____.

A. Submitter

Linvatec Corporation
11311 Concept Boulevard
Largo, Florida 33773-4908

B. Company Contact

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

C. Device Name

Trade Name:	:	Universal Drive System
Common Name	:	Drive System
Classification Name	:	Instrument, Surgical, Orthopedic, AC Powered Motor and accessory/Attachment 87 878.4820

D. Predicate/Legally Marketed Devices

Universal Drive System
Linvatec Corporation

Hall® Versipower® Plus Large Bone Instrument System
Linvatec Corporation

3M™ Maxi-Driver™ Electric Powered Instrument System
3M Health Care

E. Device Description

The Universal Drive System is a modification of the Linvatec Universal Drive System with the addition of three new handpieces used in large bone orthopedic procedures. The Universal Drive System was cleared under 510(k) #K971059 on 6/18/97 for the following intended uses: Cutting of soft tissue and bone in Orthopedic, Arthroscopic, Otolaryngological, Oral/Maxillofacial, Hand, Foot, Neuro, and Plastic/Reconstructive surgical procedures.

The Universal Drive System consists of an AC powered drive console, a sterilizable handpiece cord, various motorized handpieces, various shavers, blades, burrs, drills, routers, and a foot switch.

The modification will take place within the Universal drive console power unit. A software computer chip will be upgraded to allow the use of additional motorized handpieces for large bone orthopedic procedures. The transformer will be upgraded in order to have more available current to drive the large bone handpieces.

Three handpieces used in large bone orthopedic procedures will be added to the system. The new handpieces include a single trigger modular, dual trigger modular handpiece and an oscillating saw. These handpieces are similar in design to the Hall® Versipower® Plus handpieces. The handpieces will be sold with a detachable handpiece cord. The detachable handpiece cord will allow the handpieces to run on the same console. The new handpieces will perform as the Versipower® Plus handpieces described in the predicate information.

The accessories used with the system include shavers, blades, burrs, drills, and routers as described in 510(k)# K971059.

F. Intended Use

The Universal Drive 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, and Plastic/Reconstructive surgical procedures.

G. Substantial Equivalence

The Universal Drive System is substantially equivalent in design, function and intended use to the Universal Drive System (Linvatec Corporation), Hall® Versipower® Plus Large Bone Instrument System (Linvatec Corporation), and the 3M™ Maxi-Driver™ Electric Powered Instrument System (3M Health Care).

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 AND DISSIMILARITIES

Company	Device Name	Intended Use	System Components and Design
NEW PRODUCT Linvatec	Universal Drive System	Cut Soft Tissue & Bone during Large Bone Orthopedic Procedures.	*System consists of:* Universal Controller, Single Trigger Modular Handpiece, Dual Trigger Modular Handpiece, Oscillating Saw, Power Cord and Handpiece Cord.
PREDICATE Linvatec 510(k) #K971059	Universal Drive System	Cut Soft Tissue & Bone during Orthopedic, Oral/Maxillofacial, Hand, Foot, Neuro and Plastic/Reconstructive surgical procedures.	*System consists of:* Universal Controller, Foot Control, Sagittal Saw, Oscillating Saw, Reciprocating Saw, High Speed Drill, Medium Speed Drill, Low Speed Drill, Wiredriver/Fixation Drill and associated attachments, blades, and burs.
		To perform cutting of soft tissue and bone in the applications of : Arthroscopic/Orthopedic, Otolaryngological and Reconstructive Surgery.	*System consists of:* Universal Controller, Foot Control, "Apex style" Handpieces and associated attachments, blades, and burrs. Shaver blades & burrs: length 75-200mm, diameter 2.0-6.0mm.
PREDICATE Linvatec 510(k) #K895198	Hall® Versipower® Plus Large Bone Instrument System	Drill, Ream, and Cut large bone during Orthopedic Procedures.	*System consists of:* drills and saws which are powered either by battery or electric console.
PREDICATE 3M Health Care 510(k) K951118	3M Maxi-Driver Electric Powered Instrument System	Drill, Ream, and Cut large bone during Orthopedic Procedures	*System consists of:* Controller, handpiece, and interchangeable attachments.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 24 1998

Carol A. Weideman, Ph.D.
Linvatec Corporation
11311 Concept Boulevard
Largo, Florida 33773

Re: K981269
Trade Name: Universal Drive System
Regulatory Class: II
Product Code: HRX
Dated: April 6, 1998
Received: April 7, 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,

for 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

Linvatec

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

April 6, 1998

510(k) Number (if known): K981269

Device Name: Universal Drive System

Indications for Use:

The Universal Drive 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, 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)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K981269

Prescription Use X OR Over-the-Counter Use _____

(Per 21 CFR 801.109)

(Optional Format 1-2-96)