Linvatec

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

JUN 18 1997

K971059

March 21, 1997

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.
Manager, 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 878.4820

D. Predicate/Legally Marketed Devices

Hall MicroChoice® Electric Powered System
Linvatec Corporation

Apex® Universal Drive System
Linvatec Corporation

TPS Total Performance System
Stryker Endoscopy

Adapteur Power System™
Arthrex Inc.

E. Device Description

The Universal Drive System is a combination of the entire Linvatec MicroChoice® System and component handpieces/blades/burrs of the Apex® Universal Drive System. Both systems and their intended uses are cleared by MicroChoice 510(k) #K942660 and Apex Universal Drive System 510(k)'s #K944476 & #K964548.

The Universal Drive System consists of a 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 MicroChoice drive console power unit software. A computer chip will be upgraded to allow additional motorized handpieces from the Apex Universal Drive system for orthopedic and arthroscopic type procedures.

Three handpieces from the Apex Universal Drive System will be modified with a detachable handpiece cord. The detachable handpiece cord will allow the "Apex style" handpieces to run on the same console as the MicroChoice original handpieces. All new handpieces will perform as described in the previous 510(k) submissions.

The accessories including shavers, blades, burrs, drills, and routers from the Apex Universal Drive System will be used in addition to the MicroChoice System accessories. The shavers will have diameters of 2.0-6.0mm and lengths of 75-200mm.

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 Hall MicroChoice Electric Powered System (Linvatec Corporation), Apex Universal Drive System (Linvatec Corporation), TPS Total Performance System (Stryker Endoscopy), and Adapteur Power System™ (Arthrex Inc.).

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

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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 18 1997

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

Re: K971059
Trade Name: Universal Drive System
Regulatory Class: II
Product Code: HRX
Dated: March 21, 1997
Received: March 24, 1997

Dear Dr. Weideman:

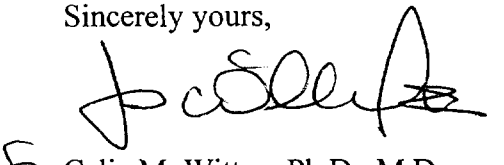
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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,



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

March 21, 1997

510(k) Number (if known): K971059

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 K971059

Prescription Use ✓ OR Over-the-Counter Use_____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)