



K964548

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Manager, Regulatory and Clinical Affairs

November 12, 1996

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 Spinal System, 510(k) Number 964548.

A. Submitter

Linvatec Corporation
11311 Concept Boulevard
Largo, Florida 33773-4908

B. Company Contact

Carol A. Weideman, Ph.D.
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C. Device Name

Trade Name: : Apex™ Universal Drive System
Common Name : Drive System
Classification Name : Surgical, ENT (electric or pneumatic), including handpiece

D. Predicate/Legally Marketed Devices

Apex™ Universal Drive System
Linvatec Corporation

XPS™ Straightshot Micro Resector System
Xomed Endoscopy

Dyonics® EP1 Surgical Drive System
Smith and Nephew Endoscopy



E. Device Description

The Apex Universal Drive system contains a drive console, micro handpiece, blades/burrs/routers and foot switches.

The forward/reverse speed is being increased to reduce the incidence of bur chatter. The oscillation speed is being modified to increase the rate of resection.

The modification will take place within the drive console power unit software. A computer chip will be upgraded to allow the handpiece to run at a higher maximum rpm in forward/reverse and oscillate mode.

F. Intended Use

The Apex Universal Drive System is utilized for shaving of soft tissue and bone during otolaryngological and reconstructive surgery. The drive system is reusable.

G. Substantial Equivalence

The Apex Universal Drive System is substantially equivalent in design, function and intended use to the Apex™ Universal Drive System (Linvatec Corporation), XPS™ Straightshot Micro Resector System (Xomed Endoscopy) and Dyonics® EP1 Surgical Drive System (Smith and Nephew 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.

Summary of Safety and Effectiveness
 Apex™ Universal Drive System
 510(k) # _____
 November 12, 1996
 Page 3 of 3

CHART OF SIMILARITIES AND DISSIMILARITIES

Company	Device Name	Intended Use	Design
NEW PRODUCT Linvatec	Apex™ Universal Drive System	ENT and Reconstructive Surgery	<u>Micro Handpiece Speed</u> Maximum Forward/Reverse: 5,000 rpm Maximum Oscillate: 2,500 rpm
PREDCATE Linvatec 510(k) # K944476	Apex™ Universal Drive System	ENT and Reconstructive Surgery	<u>Micro Handpiece Speed</u> Maximum Forward/Reverse: 3,500 rpm Maximum Oscillate: 1,500 rpm
PREDCATE Komed Endoscopy 510(k) # K862807 K954796 K960856	XPS™ Straightshot™ Micro Resector System	ENT	<u>Handpiece Speed</u> Maximum Forward/Reverse: 6,000 rpm Maximum Oscillate: 3,000 rpm
PREDCATE Smith and Nephew Endoscopy 510(k) # K954989	Dyonics® EP1 Surgical Drive System	ENT	<u>Handpiece Speed:</u> Maximum Forward/Reverse: 8,000 rpm Maximum Oscillate: 3,000 rpm