Linvatec

11311 Concept Boulevard Largo, FL 33773-4908 727-392-6464

JUN - 4 2003

K031098

April 1, 2003

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 3-CCD Digital Camera System 510(k) Number _____.

A. Submitter

Linvatec Corporation
11311 Concept Boulevard
Largo, Florida 33773-4908

B. Company Contact

Laura D. Seneff, RAC
Manager, Regulatory Affairs
(727) 399-5234 Telephone
(727) 399-5264 FAX

C. Device Name

Trade Name:	3-CCD Digital Camera System
Common Name:	3-CCD Digital Camera System
Classification Name:	Laparoscope, General & Plastic Surgery Endoscope and Accessories
Proposed Class:	Class II
Device Product Code:	GCJ

K031098

D. Predicate/Legally Marketed Devices

Linvatec Corporation
Digital 3-Chip Camera System
510(k) K970605

Stryker Endoscopy
Model 888 Video Camera
510(k) K983566

E. Device Description

The Linvatec 3-CCD Digital Camera System consists of a camera control unit and a camera head that is used in conjunction with an endoscope to allow for visualization during minimally invasive surgical procedures. Sterilization of the camera head and cable is required before use. The camera heads may be sterilized using steam sterilization.

The Linvatec 3-CCD Digital Camera System will be capable of interfacing with the ConMed I.S. Operating Room Control System with no impact on normal camera system operation.

F. Intended Use

The Linvatec 3-CCD Digital Camera System is intended for use in a variety of endoscopic surgical procedures including but not limited to orthopedic, laparoscopic, urologic, sinuscopic, plastic and as an accessory for microscopic surgery.

G. Substantial Equivalence

The 3-CCC Digital Camera System is substantially equivalent in materials, design and intended use to the predicate devices. There are no significant differences to the new device that raise issues of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 4 2003

Ms. Laura Seneff, RAC
Manager, Regulatory Affairs
Linvatec Corporation
11311 Concept Boulevard
Largo, Florida 33773-4908

Re: K031098
Trade/Device Name: 3-CCD Digital Camera System
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: GCJ
Dated: April 1, 2003
Received: April 7, 2003

Dear Ms. Seneff:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate 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) that do not require approval of a premarket approval application (PMA). 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.

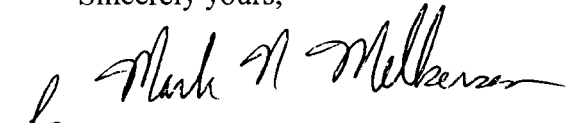
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at (301) 594-4659. 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" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer 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,



for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

April 1, 2003

510(k) Number (if known): K031098

Device Name: 3-CCD Digital Camera System

Indications for Use:

The Linvatec 3-CCD Digital Camera System is intended for use in a variety of endoscopic surgical procedures including but not limited to orthopedic, laparoscopic, urologic, sinuscopic, plastic and as an accessory for microscopic surgery.

(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)

(Optional Format 1-2-96)

Mark N Milkerson

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K031098