

K972617

1. Submitter's information

Helax AB
PO Box 1704
S-751 47 Uppsala Sweden

OCT - 1 1997

Contact person

Jan Törnqvist, Vice President RA/QM
Phone: int 46 18 565017
Fax: int 46 18 565017
E-mail jan.tornqvist@helax.se

Submission dated: 1997-07-04

2. Device Name

Common or Usual name:

Verification and Information System in Radiotherapy
(VISIR)

Proprietary Name: Helax-VISIR

Classification Names: Medical Linear Accelerator
21 CFR § 892.5050
Class II
Product Code: RA IYE

3. Predicate Device

Philips Veriflex

Verification and record system in Radiotherapy
K902849
Philips Medical Systems, Inc.
Currently owned by Nucletron Corporation

4. Description of the Device

The Helax-VISIR system is a modern product for improved treatment management and quality assurance in Radiotherapy. The increasing complexity of treatment techniques and equipment requires a flexible and vendor-independent system for the booking, set-up, verification and documentation of the radiotherapy process.

5. Statement of Intended Use

Helax-VISIR is designed to be a tool for supporting the process of scheduling, preparing, setting up, delivering and recording radiation therapy. It will help administering patient sessions through the booking functionality and activity reports. It will fetch data from dose planning systems and simulators automatically or by manual



Helax AB
510(k) summary of safety and effectiveness

Date: 1997-07-04

A large part of the development, verification and validation of the Helax-VISIR medical device was performed by Helax-VISIR A/S in Oslo, Norway, a fully owned subsidiary to Helax AB. The development was performed according to Helax AB Quality System and controlled by Helax AB.

The device and its development process also comply with the FDA, CDRH, ODE, August 23, 1991, Reviewer Guidance for Computer Controlled Medical Devices Undergoing 510(k) Review

Performance tests were conducted and the results indicated that the system consistently performed within the design parameters and equivalently to the predicate device.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT - 1 1997

Jan Tornqvist
Vice President, Regulatory Affairs and Quality Management
Helax AB
Klostergatan 12
Uppsala, Sweden

Re: K972617
Helax-VISIR (Verification and Information
System in Radiotherapy)
Dated: July 4, 1997
Received: July 9, 1997
Regulatory class: II
21 CFR 892.5050/Procode: 90 IYE

Dear Mr. Tornqvist:

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) 594-4613. 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/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

510(k) Number (if known): K972617

Device Name: Helax-VISIR

Indications For Use:

Patients undergoing radiation treatment
according to prescribed treatment plan.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF
NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)

David G. Seymour
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices

510(k) Number K972617