

1. Submitter's information

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Contact person

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Submission dated: 1998-08-11

2. Device Name

Common or Usual name:

Helax-IMCON Simulator Workstation
(IMCON)

Proprietary Name: Helax-IMCON

- Standard Product Nomenclature: System, Image Processing
- Regulation number: 21 CFR § 892.
- Class: II
- Product Code: 90LLZ

3. Predicate Device

Varis Images, Including Ximatron Digital Imaging (K952313).

Product is owned by Varian Associated Inc., 3045 Hanover Street, Palo Alto CA 94304-1129, USA.

4. Description of the Device

Helax-IMCON is an image workstation that replaces the fluoroscopic monitor at a radiotherapy simulator. It is connected to the video signal from the image intensifier of the simulator and the X-ray images are captured by a frame grabber and converted to digital images.

5. Statement of Intended Use

Helax-IMCON is designed to be a tool for supporting the process of Radiotherapy treatment planning utilising simulator images. Helax - IMCON supports both the

planning of a radiotherapy treatment and the verification of an established treatment plan.

Helax- IMCON is used to define the field size and shape for the radiotherapy treatment of a patient, based on an image or series of merged images taken at the simulator. If the simulator has been equipped with the Helax-IMCON LCD panel these shapes can be projected onto the patient. Defined parameters can be exported to the clinics verification system or to the accelerator.

Helax-IMCON is also used for verification of a treatment plan prepared with a treatment planning system as Helax-TMS. The treatment plan will be imported at the Helax-IMCON workstation. Helax-IMCON will then overlay the planned field size and shape on the image for verification purposes.

Helax - IMCON is intended to be operated by radiographers ,physicists and physicians skilled in radiation therapy and trained in using the system.

The intended use is the same as the predicate devices.

6. Statement of Technological Characteristics

The predicate device is presently in commercial distribution in the United States. The Helax-IMCON has the same technological characteristics and is similar in design, function, and application to the predicate device.

The Technological Characteristics are the same as the predicate device.

7. Differences

There are no differences between the technology of the predicate device and the Helax-IMCON and only minor differences in configuration and specifications as noted in the predicate device comparison chart. These differences do not alter the intended use or affect the safety and effectiveness of the Helax-IMCON system when used as labelled.

8. Special controls

Although there are no performance standard established by the FDA for these devices the Helax-IMCON is designed, and manufactured to meet, the following standards:

- IEC 601-1 Electrical medical equipment - General requirements for safety
- IEC 601-1-4 Electrical medical equipment -Part 1: General requirements for safety
- 4. Collateral Standard: Programmable electrical medical systems.
- IEC 1217 Radiotherapy equipment - Coordinates, movements and scales
- IEC 878 Graphical symbols for electrical equipment in medical practice

Helax AB is certified according to European EG Medical Device Directive, Annex II Section 3.2 - Full Quality Assurance System, per 1997-01-08. The scope of the certification is: Design, development, production, installation and servicing of based systems in oncology in class IIb. Helax AB Quality System is also certified according to the requirements in ISO 9001 and EN 46001.

The Helax-IMCON product was developed by Helax AB. Part of the development work was done by Image Connectivity Sweden AB (ICS), under the control by Helax AB.

The Helax-IMCON product will be released, marketed, produced, serviced and maintained by Helax. A complete Device Master Record will be prepared, maintained and approved by Helax according to Helax procedures. The Helax-IMCON product will be a part of the Product Area VIS within Helax.

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.



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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850Jan Tornqvist
Vice President, Regulatory Affairs
Helax AB
Klostergatan 12
Uppsala, SwedenRe: K982857
Helax-IMCON Version 1.0
Dated: August 11, 1998
Received: August 13, 1998
Regulatory class: II
21 CFR 892.5840/Procode: 90 KPQ

Dear Ms. 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 requirements, 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/dsma/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): K982857

DEVICE NAME: Helax-IMCON version 1.0

INDICATIONS FOR USE:

Patients planned for radiation treatment,
either to verify a prescribed plan, or to help
at the planning at the simulator.

(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 K982857