DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 17 1999

Terry Chwalk
Executive Vice President
Huestis Medical
68 Buttonwood Street
Bristol, RI 02809

Re: K981153
OSIRIS (Patient Verification and Contouring System)
Dated: December 11, 1998
Received: December 18, 1998
Regulatory class: II
21 CFR 892.5050/Procode: 90 IYE

Dear Mr. Chwalk:

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 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). 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,

CAPT Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

HUESTISMEDICAL

Ver/3 – 4/24/96

Huestis Medical
68 Buttonwood Street
Bristol, RI 02809

510(k) Number: K981153

"OSIRIS" Patient Position Verification and Contouring System

Indications for Use:

The OSIRIS optical outline system is used to measure patient contours for the purpose of radiotherapy treatment planning. Its main applications are for breast and abdomen treatment planning. The system utilizes existing Simulator or Therapy Room patient alignment lasers to generate visible surface anatomy shape contours.

The professional groups using the OSIRIS system can include Medical staff, radiographers, technicians and medical physicists – all of whom are professionally employed within a radiotherapy department and are specialists in the use of surface contours for radiotherapy treatments. The main users are those who use Radiotherapy Simulators for treatment simulation and verification, and the staff who treat patients on linear accelerator therapy machines. The same groups of staff will use the surface contours for isodose production, where appropriate, and define the setup data and any additional measurements required, according to the QA programs running in that department.

Typical application is in the measurement and calculation of missing tissue compensator filters.

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K981153

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ **OR** Over-The-Counter _____

(Per 21 CFR 801.109)

(Optional Format 1-2-96)