

MAR 22 2000

510(k) Summary

RadioCameras™ System Head/Neck Application

- I. Company:** Surgical Navigation Technologies
Contact: Angelique Destruel
530 Compton St.
Broomfield, CO 80020
(303) 439-9709
- II. Product Name:** RadioCameras™ System Head/Neck Application
- III.** This submission describes a system that is intended to be used to place patients at the isocenter of a linear accelerator for stereotactic radiosurgery or radiotherapy procedures on head and neck lesions outside the cranium. The RadioCameras™ Head/Neck Application uses fiducial markers on a biteblock to localize the treatment site on CT or MR scans and optical tracking of infrared markers on the biteblock as the method of locating the position of the treatment isocenter relative to the LINAC isocenter. The RadioCameras™ Biteblock System Head/Neck Application consists of a high resolution linear CCD camera array, computer workstation, a biteblock optical positioner, and an optical calibration jig.
- IV.** The RadioCameras™ Biteblock System Head/Neck Application is indicated for use with a Linear Accelerator to perform Stereotactic Radiosurgery or Radiotherapy on lesions in the head/neck region outside the cranium. The RadioCameras™ Head/Neck Application provides precise positioning of the treatment target at the Linear Accelerator's isocenter.
- V.** The RadioCameras™ System Head/Neck Application was shown to be substantially equivalent to commercially available localization and positioning systems for use in conjunction with linear accelerator-based stereotactic radiosurgery and radiotherapy.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 22 2000

Angelique Destruel
Clinical and Regulatory Affairs Associate
Surgical Navigation Technologies
530 Compton Street
Broomfield, CO 80020

Re: K994355
RadioCameras™ System Head/Neck Application
Dated: December 21, 1999
Received: December 23, 1999
Regulatory class: II
21 CFR 892.5050/Procode: 90 IYE

Dear Ms. Destruel:

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) 594-4591. 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 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,

Daniel G. Schultz, M.D.
Captain, USPHS
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure(s)

510(k) Number (if known):

Device Name: RadioCameras™ Biteblock System Head/Neck Application

Indications For Use:

The RadioCameras™ Biteblock System Head/Neck Application is indicated for use with a photon linear accelerator to perform Stereotactic Radiosurgery or Radiotherapy on head and neck therapeutic targets that lie outside the cranium. It provides precise positioning of the treatment target at the Linear Accelerator's isocenter.

(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 A. Seymour
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K994355