

**510(k) Summary of Safety & Effectiveness
for the
Radionics TLC Pediatric Frame**

K991523

1. Sponsor

Radionics Software Applications, Inc.
22 Terry Avenue
Burlington, MA 01803

Contact Person: Nancy C. MacDonald
Sr. Regulatory Engineer
(781) 272-1233

2. Device Name

Proprietary Name: TLC Pediatric Frame
Common/Usual Name: Stereotactic Radiation Treatment Planning
System and Accessories
Classification Name: X-ray Radiation Therapy System

3. Predicate Device

Radionics Software Applications, Inc. believes that within the meaning of the Medical Devices Amendments of 1976, the TLC Pediatric Frame addressed in this premarket notification is substantially equivalent to the following medical device:

The Radionics Gill-Thomas-Cosman (GTC) Re-locatable Head Holder System, cleared under 510(k) #K934523.

4. Device Description

The TLC Pediatric Frame is a Re-locatable Head Holder System. The device consists of a base frame that combines the attachment of various sized plastic occipital head cups, left and right earplug tips, and a mold of the patient's frontal, nasion and lateral of eyes. The Radionics' Depth Helmet attaches to the frame and depth measurements are maintained to allow the operator to re-locate the patient for each radiation therapy treatment.

5. Intended Use

The TLC Pediatric Frame is intended for use as a stereotactic platform for fractionated (multiple, lower dose) LINAC-based radiation treatments and related CT and angiographic imaging in the cranium for the treatment of pediatric patients.

6. General Safety and Effectiveness

The TLC Pediatric Frame labeling contains Instructions for Use. The Operator's Manual includes: indications for use, cautions, warnings and user quality assurance procedures. This information promotes safe and effective use of this device.

7. Comparison of Technological Characteristics

Radionics Software Applications, Inc. believes that the information and testing provided in this submission clearly describes the technological characteristics of the TLC Pediatric Frame and demonstrates that the TLC Frame is substantially equivalent to the commercially available GTC Re-locatable Head Holder System.

8. Performance Testing

Non-clinical tests were conducted to demonstrate that the TLC Pediatric Frame meets all product requirements. This testing also demonstrates that the performance is substantially equivalent to the predicate device cited above.

9. Safety Summary

The TLC Pediatric Frame has quality assurance equipment and procedures to verify, prior to patient treatment, that the TLC Frame is accurately positioned with respect to the patient's cranium.

10. Basis for Substantial Equivalence

The TLC Frame, addressed in this premarket notification, has the same technological characteristics as the commercially available Radionics GTC Re-locatable Head Holder System. Like the GTC, the TLC Frame is non-invasive, and allows repeat positioning for lower dose multiple fractionated stereotactic LINAC-based radiation treatments and related CT and angiographic imaging.



JUL 30 1999

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Nancy MacDonald
Senior Regulatory Engineer
Radionics Software Applications, Inc.
22 Terry Avenue
Burlington, Massachusetts 01803-2516

Re: K991523
TLC Pediatric Frame
Dated: April 30, 1999
Received: May 3, 1999
Regulatory Class: II
21 CFR 892.5050/Procode: 90 IYE

Dear Ms. MacDonald:

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

510(k) Number (if known):

Device Name: TLC Pediatric Frame

Indications for Use:

The TLC Frame is indicated for use as a stereotactic platform for fractionated (multiple, lower dose) LINAC-based radiation treatments and related CT and angiographic imaging in the cranium for the treatment of pediatric patients.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Bergman
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K991523

Prescription Use:
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____