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# 510(k) Summary of Safety and Effectiveness for BrainSCAN

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BrainLAB

## 1. Company


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## 2. Device Name

Trade name: BrainSCAN XL, BrainSCAN Classic, Novalis Treatment Planning
Common name: BrainSCAN
Current version number: 5.0
Classification name: X-ray radiation therapy system (per 21CFR892.5900)

## 3. Predicate Devices:

BrainSCAN Radiosurgery Module (K920879)
BrainSCAN Conformal RT Module (K971367)

## 4. Device Description

BrainSCAN is a software program to generate treatment plans and to simulate the dose delivery for external beam radiotherapy. BrainSCAN is the evolutionary successor of the predicate devices and is a treatment planning software specialized for stereotactic procedures for cranial as well as extracranial lesions. It includes functions for all relevant steps from image viewing to quality assurance. BrainSCAN is developed for the Windows NT operating systems and is tested and released for Alpha and Intel processor platforms.

BrainSCAN incorporates all capabilities of the predicate devices and extends some of them. BrainSCAN allows aligning of two image sets of different imaging modalities automatically to obtain a common coordinate system for both. It allows defining a stereotactic coordinate system for treatment of extracranial lesions using the patient positioning system ExacTrac. To account for tissue inhomogeneities the possibility to calculate dose with a pencil beam algorithm is added. If the pencil beam algorithm is used it is possible to calculate the dose distribution of intensity modulated beams. BrainSCAN further extends the capabilities of the predicate devices to export treatment plans with the possibilities to export plans to the archive and verification system of Varian (VARiS) and to generate ASCII-files for the import into the archive and verification system of Impac (Lantis/Impac).

## 5. Intended Use

BrainSCAN is a stereotactic radiation treatment planning system with the same intended use as the commercially available BrainSCAN Radiosurgery and BrainSCAN Conformal RT modules. It is intended for use in stereotactic, conformal, computer planned, LINAC based radia-

tion treatment of cranial, head and neck, and extracranial lesions. It is intended to be used by experienced and trained health professionals.

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## 6. General Safety And Effectiveness

The different subsystems of the BrainSCAN software have been thoroughly tested on subsystem level and an extensive integration test of the submodules was performed. Numerous tests that were derived from a complete risk analysis and assessment have been performed as well. Dosimetric as well as cross checks with other treatment planning systems have been performed to verify the implementation and performance of the pencil beam algorithm. The training and installation session provides assurance that the user understands all aspects of the BrainSCAN system: mechanical, computer and software, plus its intended functionality.

## 7. Technological Characteristics

The information and testing provided in this submission clearly describes the technological characteristics of the BrainSCAN modifications and additional features and demonstrates that BrainSCAN is substantially equivalent to the commercially available predecessors BrainSCAN Radiosurgery Module and BrainSCAN Conformal RT Module.

BrainSCAN is a stereotactic radiation treatment planning system that allows the 3D definition of objects based on patient images obtained from various imaging modalities. It offers several tools to the user to allow optimizing the dose distribution to spare healthy tissue and to escalate the dose in the planning target volume.

To summarize the additional features:

- Pencil beam dose calculation for increased accuracy in extracranial applications
- Intensity modulated fields for optimized dose distribution shaping
- Stereotactic coordinate system for the whole body in conjunction with ExacTrac
- Automatic image fusion to superimpose two image sets from different imaging modalities
- Treatment plan export to VARiS, the record and verify system of Varian
- Treatment plan export to LANTIS and Impac, the record and verify system(s) of Impac

## 8. Substantial Equivalence

Documentation was provided which demonstrated the BrainSCAN software to be substantially equivalent to its predecessor versions BrainSCAN Radiosurgery Module and BrainSCAN Conformal RT Module.

## 9. Patient Relevant Safety Information

The predecessor devices of BrainSCAN have been used in over a hundred installations worldwide and thousands of patients have safely been treated using the predicate devices of BrainSCAN in clinics like the University of California, Los Angeles. All new features were introduced to improve the resulting quality of the treatment plans further and to enhance the possibilities the oncologist has to develop strategies for radiation treatment.

All treatment plans generated with BrainSCAN have to be approved by signature of a radiation physicist and a physician, normally a radiation oncologist, prior to treatment. This ensures that the plan is correct from the point of view of the physician with his medical background and the point of view of the physicist with his radiation physics background.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 1 3 2000

Claus Promberger
Project Manager
BrainLab AG
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855551 Heimstetten
Germany

Re: K994413
BrainScan (X-ray Radiation Therapy System)
Dated: April 20, 2000
Received: April 24, 2000
Regulatory class: II
21 CFR 892.5050/Procode: 90 MUJ

Dear Mr. Promberger:

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): K994413

Device Name: BrainScan

Indications For Use:

BrainSCAN is a stereotactic radiation treatment planning system that is intended for use in stereotactic, conformal, computer planned, LINAC based radiation treatment of cranial, head and neck, and extracranial lesions.

(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. Shyman

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K994413