DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 17 1999

Mr. Rainer Birkenbach
Executive Vice President
Brainlab USA, Inc.
3100 Hansen Way
Building 4A, Mailstop E233
Palo Alto, California 94304

Re: K983410
Trade Name: @TARGET
Regulatory Class: II
Product Code: HAW and KXK
Dated: June 21, 1999
Received: June 24, 1999

Dear Mr. Birkenbach:

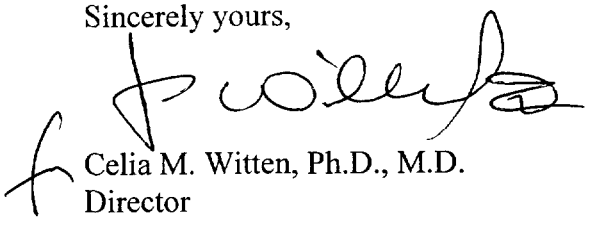
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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 requirement, 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) 594-4595. 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/dsmamain.html".

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K983410

Device Name: @Target

Indications For Use:

## SURGERY PLANNING

The SURGERY PLANNING module is a tool for pre- and intraoperative stereotactic surgery planning based on stereotactic systems. Multiple graphical display functions and 3-dimensional views of anatomical structures offer an effective and efficient means of presenting the anatomical data for diagnostic and surgical planning. The module provides possibilities to combine and process image data sets from CT, MRI, Angiographic, and other imaging sources. Computer-graphic simulation in various views of a chosen probe path can help prevent probe intersections with unwanted, critical structures or vessels. The surgeon can interactively change a probe path simulation through the image slices in the workstation with on-line calculation of the accompanying arc settings and graphical manipulation to aid in optimizing his approach. Its modular design makes possible adaption to the user's special requirements.

(p.t.o.)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K983410

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Device Name: @Target

## BRACHYTHERAPY

This module, based on SURGERY PLANNING, is designed for computergraphic calculation of isodoses from implantation of radioactive seeds, implanted at given positions within a tumor volume. The radioactive seeds are loaded into catheters that are implanted stereotactically. The computer software calculates the isodose profiles in various views or in three dimensions prior to actual seed implantation. The positioning of the catheters and the indwelling seeds can be displayed in several contours, each perpendicular to the direction of the implanted catheters. The objective is to better tailor the dose distribution to the 3 dimensional volume of the tumor. The relevant implantation positions and other parameters can be printed out for a hardcopy documentation of what has been done.

## BRAINMAP

The BRAINMAP module is a tool, which defines two and three-dimensional information about anatomical structures of the human brain for pre- and intraoperative planning of stereotactic procedures.. These contours are defined and described by Talairach/Tournoux and/or Schaltenbrand/Wahren based brain atlases.
The user is provided with information about the position of the various functional and anatomical areas of the brain. These positions of the structures have to be correlated with every patients brain data.
The correlation is defined by a procedure defined by Talairach/Tournoux. Using their grid system to divide the brain in particular areas, the program will be able to provide matching data for different patient data. BrainMAP may be used alone or in conjunction with neurosurgery, radiotherapy and radiosurgery planning systems.

## FUNCTIONAL PLANNING

The FUNCTIONAL PLANNING Module is a tool based on SURGERY PLANNING , which gives two- and three dimensional online information of a stereotactical surgical instrument (electrodes) for a neurosurgical functional treatment using a stereotactic arc. The user is provided with information by numerical results and by various displays and reconstruction planes based on patient images (CT, MRI, PET, SPECT) about the position and orientation relative to the patient of his surgical instrument to perform stimulation and treatment on brain structures or to a preplanned trajectory .
The software is capable of displaying the trajectory and functional areas of the brain based on BRAINMAP online on the screen and recording the stimulations by storing positions of the electrodes.
The FUNCTIONAL PLANNING module is intended to be used with patients where measurement, stimulation and placement of electrodes in the brain (pallidotomy) are part of the treatment. The stereotactic arc system is useful for placing these electrodes or using the instruments during the treatment and in the planning phases of the functional treatment.

(Division Sign-Off)
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510(k) Number K983410

Prescription Use X
(Per 21 CFR 801.109)