SEP 25 2007

# 510 (k) Summary of Safety and Effectiveness for the BrainSUITE NET

**K070556**

**Manufacturer:**


Address: BrainLAB AG
Kapellenstrasse 12
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Germany
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Contact Person: Mr. Per Persson


Summary Date: January 31, 2007

**Device Name:**

Trade name: BrainSUITE NET

Common/Classification Name: Instrument, stereotaxic

**Predicate Devices:**
**Smith & Nephew Control Digital Operating Room System (K050209)**
**Stryker Switch Point Infinity (K033132)**

Device Classification Name: Instrument, stereotaxic
Regulatory Class: Class II

**Indications for Use:**
BrainSUITE NET from BrainLAB is a platform for the integration of devices and for the distribution of video signals and multimedia content. It is intended to be used for communication between compatible BrainLAB devices.

it provides centralized access for managing video data, medical images and patient data.

BrainSUITE NET can be used in the operating theater for various surgical procedures involving video processing, image recording, patient data viewing and software application control.

**Device Description:**
BrainSUITE NET enables full control of video signals from a single touchscreen interface and display of pre-, intra- and post-operative patient data. Physicians can easily manipulate how and where information is displayed, to monitors for the entire OR team or to remote rooms for consulting and real-time education.

Video Data Management and Documentation

A wide range of video signals, e.g. from the microscope or endoscope, can be routed to displays within or outside the operating room. Preconfigured layouts can be chosen to facilitate the initial routing setup. Additionally, users can choose viewing modes for displays, for example "Picture-in-picture", "Tile View", "Quad View", etc.
For documentation purposes, screenshots can be taken from every available video source and saved for later consultation. PAL and NTSC signals may also be recorded on DVD.

Touchscreen based Centralized Access
Every device can be used inside and outside the sterile field from a single touchscreen. Users can switch from one device to another through a system wide identical user interface.

If necessary, the same device can also be used simultaneously with multiple touchscreens. For security and safety reasons, certain access schemes can be defined, especially to exclude interference with the surgeon while he is performing a critical procedure on the patient.

**Substantial equivalence:**
BrainSUITE NET has been verified according to BrainLAB's procedures for product design and development. The evaluation proves the safety and effectiveness of the system. The information provided by BrainLAB in this 510(k) application was found to be substantially equivalent with the predicate devices **Control Digital Operating Room System** (K050209) manufactured by **Smith & Nephew**, and **Switch Point Infinity** (K033132) manufactured by **Stryker**.

BrainLAB's BrainSUITE Net conforms to the following voluntary standards:

- IEC 60601-1-1:2000 Medical Electrical Equipment - Part 1: General Requirements for Safety; Safety Requirements for Medical Electrical Systems
- IEC 60601-1-2:2001 Medical Electrical Equipment - Part 1: General Requirements for Safety; Electromagnetic Compatibility

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

BrainLAB AG
% Mr. Ranier Birkenbach
Executive Vice President
Kappellenstrabe 12
85622 Feldkirchen Germany

SEP 25 2007

Re: K070556
Trade/Device Name: BrainSUITE NET
Regulation Number: 21 CFR 882.4560 and 21 CFR 876.1500
Regulation Name: Stereotaxic instrument and Endoscope and accessories
Regulatory Class: II
Product Code: HAW, GCJ
Dated: September 10, 2007
Received: September 10, 2007

Dear Mr. Birkenbach:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

# Indications for Use

510(k) Number (if known): K070556

Device Name: BrainSUITE NET

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Prescription Use ___X_____ (Per 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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

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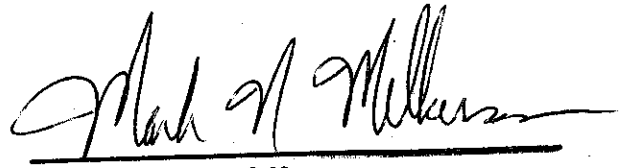
Concurrence of CDRH, Office of Device Evaluation (ODE)



**(Division Sign-Off)**
**Division of General, Restorative, and Neurological Devices**

**510(k) Number** K070556