

JUN 25 1999

**INTEGRATED
SURGICAL SYSTEMS**



K991081

SUMMARY OF SAFETY AND EFFECTIVENESS

- 1.0 **DEVICE NAME** (Trade, common, and classification): Frameless NeuroMate Stereotactic System.
- 2.0 **PREDICATE DEVICE(s)**: K963256.
- 3.0 **DESCRIPTION**: A stereotactic system with an electromechanical, multijointed arm for spatial positioning and orientation of an instrument holder or tool guide. Guidance is based on a preoperative plan developed with three-dimensional imaging software and utilizes ultrasonic registration. The system is intended for use by neurosurgeons to guide standard neurosurgical instruments.
- 4.0 **INTENDED USE**: A computer-controlled image-guided electromechanical multijointed arm, intended to be used in a neurosurgical operating room for the stereotactic spatial positioning and orientation of an instrument holder or tool guide to be used by the surgeon to manually guide standard neurosurgical instruments, under a surgeon-developed, carefully prepared stereotactic treatment plan.
- 5.0 **INDICATION FOR USE**: Stereotactic spatial positioning and orientation of an instrument holder or tool guide to be used by a surgeon to manually guide standard neurosurgical instruments.
- 6.0 **BASIS OF REQUEST**: The following factors are the basis of our request for a finding of substantial equivalency:
 - 6.1 No substantive change in materials, basic components, or method of manufacture between this device and the predicate device; the system and its components have been used in the medical device industry for similar or identical products and for similar or identical uses with no record of any patient problems, adverse reactions;
 - 6.2 No change in basic construction;

- 6.3. The device and its components have been tested by independent labs for EMC and safety, EU standards compliance, and will be subjected to inspection and testing at IQA, and during/after manufacture and upon installation in the field; and
- 6.4. The function and use of this product will be no different than that of predicate devices and other similar devices currently in the marketplace.
- 7.0 **SUBSTANTIVE DIFFERENCES:** No substantive differences exist between the product defined in this 510(k) submission and the predicate device, except the registration system, which is similar to that currently used in other medical devices, and the incorporation of a commercially available imaging software for stereotactic planning, which has been developed, verified and validated to applicable standards, and guidance documents, cited herein.

Signed:  Dated: 3/29/99

RD Hibbert
Director of Clinical and Regulatory Affairs
Integrated Surgical Systems, Inc.
1850 Research Drive
Davis, CA 95616
Phone: 530-792-2621 Fax: 530-792-2690



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 25 1999

Mr. R. D. Hibbert
Director Clinical and Regulatory Affairs
Integrated Surgical Systems
1850 Research Park Drive
Davis, California 95616

Re: K991081
Trade Name: Frameless NeuroMate Stereotactic System
Regulatory Class: II
Product Code: HAW
Dated: March 29, 1999
Received: March 31, 1999

Dear Mr. Hibbert:

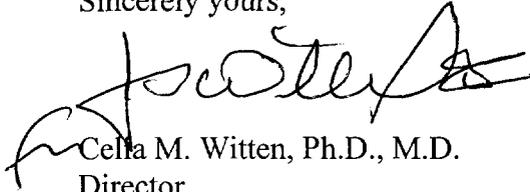
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of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

A handwritten signature in black ink, appearing to read 'C. Witten', written over the typed name.

Cella 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): _____

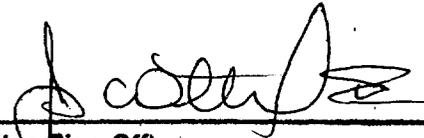
Device Name: Frameless NeuroMate

Indications For Use:

Stereotactic spatial positioning and orientation of an instrument holder or tool guide to be used by a surgeon to manually guide standard neurosurgical instruments.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)

Division of General Restorative Devices

510(k) Number _____

1991081

Prescription Use XX
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____