COMPASS INTERNATIONAL
Cascade Business Park - 919 37th Avenue NW - Rochester, MN 55901

K964229

AUG 19 1997

510(k) SUMMARY*
of
SAFETY and EFFECTIVENESS

A. General Information

Submitter's Name:	COMPASS International, Inc.
Address:	919 37th Avenue NW Rochester, MN 55901
Telephone:	507-281-2143
Fax:	507-281-1736
Contact Person:	Debrah A. Fisher, RAC
Date Prepared:	August 14, 1997

B. Device

Name:	Regulus™ Navigator
Trade Name:	Regulus™ Navigator
Common Name:	Intraoperative Guidance Device
Classification Name:	Stereotactic Instrument
Product Code:	84 HAW
Class: II	

C. Identification of Predicate Devices

The Regulus Navigator (RN) as described in this submission is substantially equivalent to the Regulus Measurement Unit (RMU), K935456, which is currently manufactured and marketed by COMPASS International, Inc. The RN also incorporates some of the features that were previously provided by the COMPASS Stereotactic Positioning System, K871046.

The RN incorporates components that are substantially equivalent in function and accuracy to other legally marketed devices including the ISG Family of Viewing Wands, K960714.

D. Description of the Device

1. *Description:*

The Regulus Navigator (RN) incorporates preoperative CT and MRI images into a surgical computer system. A minimum of three points (reference markers or anatomical points) are selected with the RN on the patient in the operating room (OR space) and the corresponding locations on the images (image space) are determined and selected by the surgeon. These corresponding points in the OR space and the image space are utilized to calculate a "transformation matrix" which is used to transform the location of the RN instrument into the image space. The location of the RN instrument is interactively displayed as a cursor on the diagnostic images and then used as a tool to guide the surgeon during the intra/extracranial procedure.

The Regulus Navigator has many components and accessories. Components are pieces of the RN which are necessary to perform any surgical procedure. Accessories are additional equipment that allow for adaptation to other surgical systems (COMPASS Stereotactic System, etc.), enable another registration method and provide for phantom maintenance testing.

Regulus Navigator Components

Magnetic Field Digitizer -- the location of the surgical field can be defined in the digitizer's coordinate system using the RN, providing the basic function of a conventional stereotactic system. Registration of CT and/or MRI images to the digitizer coordinate system (in OR space) requires locating "reference locations" in the images whose location can be determined in the digitizer's coordinate system in the operating room.

Regulus Treatment Planning Software -- software that allows a surgeon to pick target points and define tumor boundaries from radiological data and interactively track instrument location. Features include:

Tip Location (single and MPR): this function allows the positioning of an instrument anywhere in the surgical field and view its corresponding location on the closest pixel on closet CT or MRI images in interactive fashion (can be done with single slice or multiplanar reconstructions).

Tips-Eye View (single and cine loop): this function allows the projection of an instrument's trajectory onto either the currently Active target slice or all of the images in a series in a cine loop.

Computer Workstation -- a computer system which runs the treatment planning software and displays CT/MRI images.

Regulus Instruments -- the RN utilizes instruments such as a pointer tip and/or a suction tip.

Regulus Navigator Accessories

Accessories include -- radiolucent adhesive radiographic markers (to affix to a patient's head as fiducial markers), a locking mobile metal cabinet for housing the magnetic field digitizer and computer workstation, a mobile wheel stand, a 3 Point Pinion headholder adaptor, a transmitter mount, a yoke assembly (for use with the COMPASS Stereotactic System only), RS-232 cables and a CT/MRI Test Phantom (for testing accuracy of the RN system)

The design, materials, manufacturing processes and specifications of the RN are similar to the legally marketed device, the Regulus Measurement Unit (RMU) and do not raise any unresolved issues relating to safety and/or effectiveness.

E. Intended Use Statement

The Regulus™ Navigator (RN) is an intraoperative guidance device which uses reference markers or anatomical references to localize the surgical field. The RN is for intra/extracranial usage.

F. Substantial Equivalence

The RN is substantially equivalent to the Regulus Measurement Unit (RMU) and the ISG Viewing Wand in terms of its technology, accuracy and intended uses. A direct comparison of significant technology characteristics for these predicate devices and the RN is summarized below. Differences that exist between these devices, relating to technical specifications, materials, physical appearance and design do not affect the relative safety and effectiveness of the RN.

Technological Characteristics Summary/Comparison Table

Regulus Measurement Unit (RMU) -- legally marketed predicate device, K935456
ISG Viewing Wand - legally marketed predicate device, K960714
Regulus Navigator (RN) -- 510(k) Submission, K964229

Parameter	RMU	ISG Viewing Wand	RN
Headframe	Yes	No	No
Skull Clamp	No	Yes	Yes
Magnetic Field Digitizer	Yes	No	Yes
Reference Markers or Anatomical Points	Yes	Yes	Yes
Number of Markers/Points	3	Unknown	3 or more
Instrument Orientation/Tip Position	Yes	Yes	Yes
Software	Yes	Yes	Augmented
Transformation Error	RMS	RMS	RMS

Comparison Table Cont.	RMU	ISG Viewing Wand	RN
CT Imaging	Yes	Yes	Yes
MRI Imaging	Yes	Yes	Yes
DSA (Digital Subtraction Angiography) Imaging	Yes	No	No
Pre-operative Planning of Surgical Procedure	Yes	Yes	Yes
Intra-operative Guidance	Yes	Yes	Yes
Cross-sections for Manipulation and Guidance	Yes	No	No
Multiplanar Reconstruction Software Feature	No	Yes	Yes
Bench Testing	Yes	Yes	Yes
Clinicals	31 Subjects	Yes	221 Subjects
Tip Location Software Feature	Yes	Yes	Yes
Tip's Eye View Software Feature	Yes	No	Yes
Cine Loop Software Feature	Yes	Unknown	Yes
Peripheral Options	Yes	Yes	Yes
Memory (image manipulation)	Yes	Yes	Yes
Interfaces (data input)	Yes	Yes	Yes
O.R. Viewing	Yes	Yes	Yes
Environmental Conditions (temperature/vibration)	Yes	Yes	Yes
Regulations	Yes	Yes	Yes
Dimensions (specifications)	Yes	Yes	Yes
Archiving Methods	Yes	Yes	Yes
Lesion Location	Superficial Cranial	Cranial	Intra/Extra Cranial
Accuracy - Phantom Testing	Mean of 2.10mm	Mean of 1-2mm*	Mean of 1.02mm (CT) Mean of 1.67mm (MR)
Accuracy - Clinical Registration Testing	Mean of 2.78mm	Mean of 2.51mm*	Mean of 2.56mm

*Eric P. Sipos, M.D., Scot A. Tebo, B.S., S. James Zinreich, M.D., Donlin M. Long, M.D., Ph.D., Henry Brem, M.D., "In Vivo Accuracy Testing and Clinical Experience with the ISG Viewing Wand", *Neurosurgery*, Vol. 39, No. 1, July 1996.

G. Performance Data

1. Standards

Currently there are no applicable Performance Standards established by FDA under section 514 of the Food, Drug and Cosmetic Act

2. Non-Clinical Tests

Twelve phantom tests were performed utilizing CT scans. The average three-dimensional error over all twelve phantom tests was 1.02mm with a standard deviation of 0.16mm. Nine phantom tests were performed utilizing MRI scans. The average three-dimensional error over all nine phantom tests was 1.67mm with a standard deviation of 0.42mm. Therefore, the non-clinical testing of the RN supports the claim of substantial equivalence.

3. Clinical Registration Tests

In clinical registration testing (221 patients), the RN demonstrated an overall mean accuracy of 2.56mm with a standard deviation of 1.15mm. Registration accuracy was 5mm or less in 97% of cases.

Patients requiring conventional surgery of intra/extracranial pathology were included in the study. The only exclusion criteria was any patient with a metal object implanted in the head would be excluded from the use of MRI data in the procedure.

There were no adverse safety and/or effectiveness reports during this clinical study.

COMPASS International, Inc. believes the data in this submission supports the claim of substantial equivalence to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 19 1997

Ms. Debrah A. Fisher
Regulatory Affairs/Clinical Monitoring Assistant
COMPASS International, Inc.
919 37th Avenue, NW
Rochester, Minnesota 55901

Re: K964229
Trade Name: Regulus Navigator (RN)
Regulatory Class: II
Product Code: 84HAW
Dated: July 28, 1997
Received: July 29, 1997

Dear Ms. Fisher:

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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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) 594-4648. 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 at (301) 443-6597.

Sincerely yours,

Thomas J. Callahan

Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular, Respiratory,
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number: K964229

Device Name: Regulus™ Navigator

Indications for Use:

- Intraoperative Guidance Device to Localize a Surgical Field for Intra/Extracranial Usage

PLEASE DO NOT WRITE BELOW THIS LINE –
CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Thomas J. Callahan

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K964229

Prescription Use ✓ OR OVER-THE-COUNTER USE ____
(optional Form 1-2-96)