AUG 24 1998

K961903

Biosense, Ltd.

POB 297, Einstein Building, Etgar Street, New Industrial Area, Tirat HaCarmel,
39101 ISRAEL Tel: +972-4-576057 Fax: +972-4-571071

510(k) summary for the Magellan system - 2 May 1996

510(k) Notification submitted by:	Biosense Ltd. Einstein Building, Etgar Street, New Industrial Zone POB 297, Tirat HaCarmel, 39101 ISRAEL Tel: +972-4-576057 Fax: +972-4-571071
Contact person:	Susan J. Zachman, Director of Regulatory Affairs
Proprietary device name:	Magellan™
Classification name:	Programmable diagnostic computer (per 21 CFR 870.1425)
Common device name:	Location system
Legally marketed device to which substantial equivalence is being claimed	Biosense CARTO system 510(k) No. K954395

The Magellan system is a subset of the CARTO system.

The CARTO system consists of the location system and the viewing station for the EP application combined together in one product. The Magellan system is the same location system used in CARTO, to be sold separately for use with a range of different 510(k) approved locatable accessory devices and viewing stations for applications.

The intended use of both systems is the same: intrabody location for mapping and navigation. The specific application of the system in the case of CARTO is cardiac mapping, where the Magellan system may be used for cardiac applications as well as for other intrabody mapping and navigation applications.

The Magellan system complies with the European EMC directive; 89/336/EEC as amended by 92/31/EEC and 93/68/EEC and the CE mark may be affixed to the product.

Biosense, Ltd.

The Magellan system complies with the following standards:

IEC 601-1/1988
IEC 601-1 A1/1991
IEC 601-1 A2/1995
IEC 601-2-27/1994
EN 60601-1-2/1993

The non-clinical bench and animal testing show that the device is as safe and as effective as the previously marketed device to which it is being compared and does not raise any new questions of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Ms. Susan J. Zachman
Director Regulatory Affairs and Quality Assurance
Biosense, Limited
P.O. Box 297, 7 Etgar Street
Beit Einstein Building
Tirat HaCarmel 39101
Israel

Re: K961903
Trade Name: Magellan™
Regulatory Class: II
Product Code: HAW
Dated: May 21, 1998
Received: May 26, 1998

Dear Ms. Zachman:

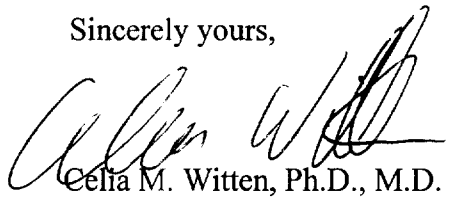
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28,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

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
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Enclosure B - Indications for Use Statement

Device Name: MAGELLAN System

510(k) Number: K961903

Indications for Use:

The MAGELLAN™ system, which is comprised of a medical workstation, a magnetic location system and a range of locatable tools is intended to be used as an image guided neurosurgery navigation system to pre-operatively and intra-operatively perform the following functions:

- process and display pre-operatively radiographic images on a monitor;
- provide intra-operative image control based on the position and orientation of a user directed tool;
- allow for the integration and usage of the Biosense magnetic location system and a range of different tool attachments; and
- store/retrieve image data on computer access media (e.g. hard disks, archive media)

Circumstances:
The MAGELLAN™ system is intended to be used during planning of a procedure, when more than one approach (e.g. entry point, trajectory, craniotomy size) is being considered, and also during surgery when:

- the target or approach is in a region with few anatomical landmarks (e.g. subcortical brain) or with complex anatomy;
- the target or approach is in a region where normal landmarks have been distorted either by disease or by previous surgery;
- the target or approach is in close proximity to critical structures) e.g. venous sinuses, air sinuses, blood vessels, nerves) which must be avoided or negotiated; or
- the target delineation is important and will not move significantly during the implementation of the approach (e.g. skull-based tumors, sinus diseases, corpus callosotomies).

Disease or Conditions:
The MAGELLAN™ system is indicated for patients who have imaged space-occupying lesions or malfunctions (both soft tissue and osseous) in the head.

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K961903

Prescription Use
(Per 21 CFR 801.109)