

SEP 3 1999

K990494

### 510(k) summary for the NOGA system

510(k) Notification submitted by: Biosense Ltd.  
Einstein Building, 7 Etgar Street, New Industrial Zone  
POB 2009, Tirat HaCarmel, 39120 ISRAEL  
Tel: +972-4-8576057 Fax: +972-4-8571071

Contact person: Lisa Wells, Regulatory Affairs Specialist

Proprietary device name: NOGA™

Classification name: Programmable diagnostic computer  
(per 21 CFR 870.1425)

Common device name: Cardiac mapping system

Cleared unmodified device Biosense NOGA system  
510(k) No. K960542

The Biosense NOGA system is designed to acquire, analyze, and display electro-mechanical maps of the human heart. The maps are reconstructed using the combination of information gathered from the integration of a plurality of intracardiac electrograms with their respective endocardial locations. In the NOGA system the location information needed to create the cardiac maps is acquired simultaneously with the local electrogram using locatable-tip catheters equipped with a Biosense sensor. The NOGA system also allows presentation of electroanatomical maps as a function of time over the cardiac cycle (electromechanical maps).

Currently, cardiac mapping is performed using a roving mapping catheter, a computerized mapping system, and fluoroscopy to determine the location of the tip of the mapping catheter. In the conventional procedure both the patient and the physician are exposed to harmful ionizing radiation during the course of the lengthy procedure.

The NOGA system enables cardiac mapping using a non-fluoroscopic catheter tip location technology. The NOGA system also uses this technology to collect additional information about the heart chamber geometry as a function of time over the cardiac cycle. Conventionally, such information would be collected using fluoroscopy or cine while injecting a radiopaque contrast agent into the heart chamber (ventriculography).

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

The NOGA 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. The use of the non-fluoroscopic location technology may reduce the exposure to dangerous ionizing radiation to the both the physician and the patient.



SEP 13 1999

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Marcia Leatham, M.D.  
VP, Clinical and Regulatory  
Biosense, Inc.  
3333 Diamond Canyon Road  
Diamond Bar, CA 91765

Re: K990494  
Modification to NOGA  
Regulatory Class: Class II  
Product Code: DQK  
Dated: August 2, 1999  
Received: August 4, 1999

Dear Dr. Leatham:

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.

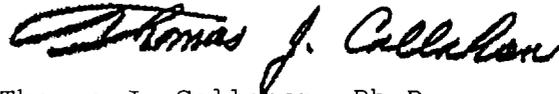
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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 pre-market 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.

Page 2 - Marcia Leatham, M.D.

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" (21CFR 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,



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

Enclosure

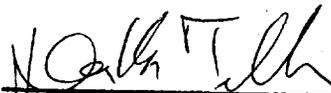
510(k) No: K960542

Device Name: NOGA System

**Indications For Use:**

The intended use of the NOGA system is catheter-based cardiac mapping.

The NOGA system allows real-time display of cardiac maps in a number of different formats. Maps may be displayed as cardiac electrical activation maps, cardiac electrical propagation maps, cardiac electrical potential maps, cardiac chamber geometry maps, cardiac dynamic maps, cardiac hemodynamic maps, and cardiac electromechanical maps. The acquired patient signals, including body surface ECG, intracardiac electrograms and intracavity or intravascular blood pressure may also be displayed in real time on the display screen.



(Division Sign-Off)

Division of Cardiovascular, Respiratory,  
and Neurological Devices

510(k) Number K990494

~~Prescription Use~~  
(Per 21 CFR 801.109)