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510(k) summary for the NOGA system - 5 February 1996

510(k) Notification submitted by: Biosense Ltd.
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Contact person: Susan J. Zachman, Director of Regulatory Affairs

Proprietary device name: NOGA™

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

Common device name: Cardiac mapping system

Legally marketed device to which
substantial equivalence is being
claimed: Biosense CARTO system
510(k) No. K954403

The Biosense NOGA system is designed to acquire, analyze, and display electro-anatomical 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 STAR catheters, which are locatable-tip catheters equipped with a Biosense sensor. The NOGA system also allows presentation of electro-anatomical maps as a function of time over the cardiac cycle.

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 recently introduced Biosense CARTO system (510(k) No. K954395) enables cardiac mapping using a non-fluoroscopic catheter tip location technology. The Biosense NOGA system is for the most part identical in design and construction to the Biosense CARTO system. The NOGA system uses the same Biosense non-fluoroscopic location technology used in the CARTO system. The NOGA system additionally uses this technology to collect additional information about the heart chamber geometry as a function of time over the cardiac cycle. Conventionally, such

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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 may be 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, and may also reduce total mapping procedure time.