SUMMARY OF SAFETY AND EFFECTIVENESS

This summary of safety and effectiveness information is being submitted in accordance with the requirements of the SMDA 1990 and 21 CFR 807.92.

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Name of the Device: ROBOGUIDE

Predicate Devices: The ROBOGUIDE is substantially equivalent to a combination of the Cytoguide manufactured by Phillips Medical and the Mammoguide manufactured by Elscint Ltd.

Description of the Device: The ROBOGUIDE is an automatic needle guidanc system that provides means for accurate positioning of a biopsy needle of a mammography system, to enable accurate penetration to sites of detectable breast lesions. The Roboguide is an attachment to and is mounted on a parent mammography system. It comprises a robotic biopsy unit and a film read out and motor control evaluation unit. After creating a stereotactic exposure of a previously detected breast lesion, the Roboguide drives a needle holder along three orthogonal axes so that the needle penetrates the precise location of the lesion. The Roboguide can be used for fine needle aspiration (FNA) or for core biopsy by interchanging its aspiration needle carrier with a biopsy gun holder carrier. The Roboguide can be used with either plain film X-ray or with a digital camera.

Comparison of Technological Characteristics: The systems share many hardware and functional characteristics :

- The biopsy units of the ROBOGUIDE and the Mammoguide are identical.
- All three units employ stereotaxis to identify the location of a breast lesion and then drives a needle carrier along three coordinate axes to a point that allows accurate placement of the biopsy needle point into the lesion.
- All three units have means for compressing and immobilizing the breast during the procedure.
- All three units employ safety mechanisms to assure no movement of the needle carrier during biopsy needle injection.

The differences between the systems raise no new issues of safety or effectiveness.

MAY, 1, 1996
Date

Mr. Jacob Gross, President