JAN 24 1997

K964460

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: ROBOLITE

Predicate Devices: The ROBOLITE is substantially equivalent to the Roboguide manufactured by the applicant Shai-Syg and is a development of the Roboguide.

Description of the Device: The ROBOLITE is an automatic needle guidance 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 ROBOLITE 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 Robolite drives a needle holder along three orthogonal axes so that the needle penetrates the precise location of the lesion. The ROBOLITE can be used for fine needle aspiration (FNA) or for core biopsy by using the regular needle carrier with a biopsy gun.
The ROBOLITE can be used with either plain film X-ray or with a digital camera.

Comparison of Technological Characteristics: The systems share almost all the same hardware and functional characteristics.

- The biopsy unit of the Robolite and the Roboguide are based on exactly the same design and construction.
- Both 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.
- Both units have means for compressing and immobilizing the breast during the procedure.
- Both units employ safety mechanisms to assure no movement of the needle carrier during biopsy needle injection.
- Both units have exactly the same evaluation unit with same drive, control and software units.

[510(k)] Summary of Safety and Effectiveness Information Supporting a Substantially Equivalent Determination

Trade Name	ABBOTT Advisor One-Step Pregnancy Test
Common Name	Consumer Use Home Pregnancy Test
Classification Name	Human Chorionic Gonadotropin (hCG) Test System
Device Classification	Class II
Predicate Device Name	FactPLUS® One Step Pregnancy Test (K962521)

The following information as presented in the 510(k) Notification for the ABBOTT Advisor One-Step Pregnancy Test constitutes data supporting a substantially equivalent determination.

Intended Use

The ABBOTT Advisor One-Step Pregnancy Test is a self-performing immunoassay designed for the qualitative determination of human chorionic gonadotropin (hCG) in urine for early detection of pregnancy.

Indications

The ABBOTT Advisor One-Step Pregnancy Test is an over-the counter *in vitro* test which can be used by the consumer to detect pregnancy as early as the first day of her missed period, using a direct urine stream sampling method. Some positive results appear as soon as three minutes, however, all results are confirmed when the Test Timer turns pink/red. The Test Timer will turn pink/red approximately 5 minutes after the urine has been added to the test device.

Device Description

The ABBOTT Advisor One-Step Pregnancy Test is an elongated device composed of two pieces of molded plastic which contain the internal test strip. The three openings on the device are the Urine Well, the Result Window and the Test Timer. The Result Window and the Test Timer are protected with a clear seal to prevent potential contamination caused by splashing urine.