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APPENDIX V

Summary of Safety and Effectiveness

DETERMINATION OF SUBSTANTIAL EQUIVALENCE

The BMI Mammotome is substantially equivalent to the Biopsys Medical predicate device. The BMI Mammotome has a substantially equivalent intended use as the predicate device. The BMI Mammotome has technologic characteristics which are substantially equivalent to the Biopsys predicate device.

COMPANY AND CONTACT PERSON

Biopsys Medical, Inc. (BMI)
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DEVICE NAME

BMI Mammotome

NAME OF PREDICATE OR LEGALLY MARKETED DEVICE

Biopsys Medical Needle

DESCRIPTION OF DEVICE

The Mammotome is comprised of a disposable needle and reusable instrument housing.

The Mammotome probe may be used with imaging guidance (such as ultrasound, X-ray, and CT), and it may be either stereotactically mounted or hand held depending on physician preference and the type of tissue sampled. The disposable Mammotome probes are available in various sizes and lengths.

The probe components include an outer trocar cannula and a sliding inner hollow coaxial cutter. The trocar cannula incorporates a distal sampling notch and a proximal notch which forms the tissue retrieval chamber. The sampling notch thumbwheel is used to manually turn and orientate the sampling notch as desired.

STATEMENT OF INTENDED USE

The BMI Mammotome is intended for diagnostic sampling of breast tissue during a biopsy procedure.

STATEMENT OF INTENDED USE OF PREDICATE/MARKETED DEVICES

The predicate device is indicated for use for removal of soft body tissue for a biopsy, definitive diagnosis, or confirmation of a clinical diagnosis.

STATEMENT OF COMPARISON OF TECHNOLOGIC CHARACTERISTICS BETWEEN DEVICE AND PREDICATE DEVICE

The BMI Mammotome has technologic characteristics which are substantially equivalent to the predicate device. In general, the disposable probes are made of stainless steel; the probes manually and mechanically pierce the tissue, cut the tissue with a hollow cutter, and collect or eject the tissue from the probe after it is removed from the body.