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510(K) SAFETY AND EFFECTIVENESS SUMMARY

Date: September 20, 1996

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Common/Ususal Name: Monopolar Electrosurgical Electrode

Proprietary Name: *Sure Core* Biopsy Electrode

Classification: Class II

Description: The *Sure-Core* Biopsy Electrode Kit consists of four components: a locator needle, a locator wire, a soft tissue dilator, and the *Sure-Core* electrosurgical core cutting electrode. The *Sure Core* Biopsy Electrode is both a manual core cutting device and a monopolar electrosurgical device that is used to cut soft tissue for the purpose of obtain a biopsy sample. The distal tip is a sharp stainless steel cutting blade which cores the tissue distal to the end of the dilator. The most difficult aspect of obtaining a true core biopsy is the detachment of the core from the remaining tissue. The *Sure-Core* Biopsy Electrode overcomes this obstacle by means of a monopolar electrosurgical wire. The electrosurgical wire cuts the tissue perpendicular to the distal blade.

Substantial Equilvalence: The *Sure Core* Biopsy Electrode and accessory items are substantially equivalent to numerous currently marketed soft tissue biopsy devices in both design features and intended use. The *Sure Core* Biopsy Electrode has similar design features as the needle assembly for the ABBI (Advanced Breast Biopsy Instrumentation) except that the ABBI is computer controlled and the *Sure Core* Biopsy Electrode is a physician controlled surgical procedure.   In addition, the *Sure Core* Biopsy Electrode is a monopolar electrosurgical electrode. The core tissue sample is detached or severed from the remaining tissue by activation of this feature. Again, numerous monopolar electrosurgical electrodes are currently marketed by Aaron Medical, Unimed Surgical, and Weck for cutting and coagulation of soft tissue.

Conclusion: The Sure Core Biopsy Electrode Kit and asseccory components are safe and effective for the intended purpose of obtaining soft tissue core biopsy samples.