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K963894

MAR 11 1997

27 February 1997

510(k) SUMMARY

The 510(k) summary information required by 21 CFR 807.92 is as follows:

- A. Classification name: Needle, aspiration and injection, disposable.

Common/usual name: Aspiration needle, probe needle, or injection needle.

Proprietary name: SmartGuide

- B. Substantial equivalence: Homer MammaLock Ultra Repositionable Breast Localization Needle (Medical Device Technologies, Inc.), Goose-Neck Snare (Microvena Corporation), Wittich Nitinol Stone Basket (Cook, Incorporated), and others.

- C. Device description: The SmartGuide is a puncturing device capable of extending an inner cannula which deflects in a curved shape.

- D. Intended use: The SmartGuide is intended for use in punctures of anatomical sites such as organs, cysts, lymph nodes, and tissue spaces, for purposes of aspiration biopsy, drainage,

injection, or fluid collection. SmartGuide can be used in punctures where non-penetrable anatomic obstacles (e.g. bone, spine) or vital structures (e.g. blood vessels, nerves) are to be avoided. The device is intended for use in radiographic environments such as CT and ultrasound.

- E. Technological characteristics: The SmartGuide is similar to predicate devices in its design, function, and intended use.

The proposed device utilizes a memory retentive nickel titanium alloy which allows one component to be extended, changing its shape.

Submitted,
FERGUSON MEDICAL
Establishment Registration Number 2937794

A handwritten signature in black ink, appearing to read "Frank Ferguson", with a long horizontal line extending to the right.

Frank Ferguson
Official Correspondent