

K962907

Surgical Group

OCT 23 1996

Baxter Healthcare Corporation  
1500 Waukegan Road  
McGaw Park, Illinois 60085 USA

847.473.1500  
FAX: 847.785.2460

**Baxter**

**XII. SMDA REQUIREMENTS**

**510(k) SUMMARY OF SAFETY AND EFFECTIVENESS**  
**FINE NEEDLE ASPIRATION NEEDLE**

Manufacturer: Baxter Healthcare Corporation  
Surgical Group  
400 East Foster Road  
Mannford, OK 74044

Regulatory Affairs Contact: Sharon Robbins  
Surgical Group  
1500 Waukegan Road MPK  
McGaw Park, IL 60085

Telephone: (847) 785-3311

Date Summary Prepared: July, 1996

Common Name: Fine Needle Aspiration Needle

Classification: Class II per 21CFR § 876.1075

Predicate Devices: Baxter Skinny Chiba Needle  
Hart Enterprises, Inc. Soft Tissue Needles

Description: The FNA needles are comprised of a cannula and stylet assembly connected to a handle for ease of insertion into soft tissues of the body.

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**XII. SMDA REQUIREMENTS (continued)**

**510(k) SUMMARY OF SAFETY AND EFFECTIVENESS  
FINE NEEDLE ASPIRATION NEEDLE**

Intended Use:

FNA needles are devices that are used to obtain samples through the aspiration of fluid (containing cells) from soft tissues such as breast, liver, kidney, pancreas and lung, etc. to analyze size, shape and structure of cells for diagnostic evaluation or monitor treatment.

Substantial Equivalence:

The Baxter FNA Needles are substantially equivalent to Baxter's Skinny Chiba Needles and to the Hart Enterprises Soft Tissue Biopsy Needle in that:

- the intended use is the same
- the performance attributes are the same

Summary of testing:

The materials used in the fabrication of the FNA needles are evaluated through biological qualification safety tests as outlined ISO 10993, Part 1 - "Biological Evaluation of Medical Devices". The biocompatibility tests performed were Cytotoxicity, Sensitization, irritation or intracutaneous reactivity, acute systemic toxicity, Hemolysis, and Pyrogenicity as required. These materials meet the requirements of the guidance and found to be acceptable for the intended use.