

K 970 563

APR 11 1997

**510 (k) SUMMARY
OLYMPUS NA-10J-1 ASPIRATION NEEDLE**

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR, Section 807.92.

Device Name: Olympus NA-10J-1 Aspiration Needle

Common/Usual Name: Biopsy Instruments

Classification Name: 21 CFR 876.1075
Gastroenterology-Urology Biopsy Instruments

Predicate Devices: Olympus NA-1C Aspiration Needle (K904667)

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**Summary Preparation
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Statement of Intended Use:

The Olympus NA-10J-1 Aspiration Needle is specifically designed to be used with the Olympus GF-UM30P ultrasound gastroscope for ultrasonically guided fine needle aspiration (FNA) within the gastrointestinal tract.