

JUL 30 1996

K962555

510(k) SUMMARY
FOR
OLYMPUS BIOPSY FORCEPS

Device Name: Olympus FB series biopsy forceps

Common/Usual Name: Biopsy Forceps for use with bronchoscopes (ENT)

Classification Name: Bronchoscopes and Accessories
21 CFR 884.4680, Class II

Predicate Device: Olympus pre-Amendment and 510(k) cleared reusable biopsy forceps.
Olympus FB Series of Reusable Biopsy Forceps (K955065)

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Summary Preparation Date: June 27, 1996

Statement of Intended Use: The Olympus biopsy forceps are intended to be used for the collection of tissue samples under endoscopic observation.

Device Description: The Olympus biopsy forceps are specifically designed for tissue collection within the respiratory organs. The FB series of biopsy forceps are substantially equivalent in intended use, method of operation, and safety to pre-Amendment and 510(k) cleared reusable biopsy forceps.