

K970184

APR 11 1997

**510 (k) SUMMARY
OLYMPUS UES-20 ELECTROSURGICAL SYSTEM**

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 UES-20 Electrosurgical System and its associated accessories.

Common/Usual Name: Electrosurgical Units

Classification Name: 21 CFR 878.440, Class II
Electrosurgical Cutting and Coagulation Device and Accessories.

21 CFR 876.4300, Class II
Endoscopic Electrosurgical Unit and Accessories.

Predicate Devices: Olympus UES-10 Electrosurgical Unit (K911904)

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Summary Preparation

Date: January 15, 1997

Statement of Intended Use:

UES-20 Electrosurgical Unit

The Olympus UES-20 has been designed for use in medical facilities under the supervision of a trained physician. It has been designed for general and endoscopic electrosurgery (cutting and coagulation) in conjunction with Olympus designated electrosurgical accessories, endoscopes (fiberscopes, videoscopes, and rigid scopes) applicable to electrosurgery, light sources and ancillary equipment. Do not use the instrument for any purpose other than its intended use.