

K955650

510(k) Summary
for
Olympus SD Series of Reusable Electrosurgical snares

Device Name: Olympus SD snares

MAR 29 1996

Common/Usual Name: Snares

Classification Name: Endoscope Electrosurgical Unit and Accessories
21 CFR 876.4300

Predicate Devices: Olympus SD-1/2/3/4/5/6 pre-Amendment electrosurgical snares
and Olympus SD-14/15 sterile disposable snares.

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Summary Preparation Date: November 10, 1995

Summary Revision Date: February 27, 1996

Statement of Intended Use: The SD series of snares and the predicated snares are all
designed to endoscopically resect tissue from within the GI tract.

Device Description: The SD series of snares and the predicated snares are all
designed to endoscopically resect tissue from within the GI tract.
The SD snares consist of a proximal end control handle, an
electrical connection cord (A-cord), a flexible catheter-like tube,
and a distal end snare loop.

The detachable control handle contains the electrical connections
which permit the snare loop to be connected to an electrosurgical
generator via the A-cord.

The distal end snare loop may be positioned around the target
tissue by movement of a slider on the control handle. The tissue
is resected by a combination of mechanical strangulation and
electrosurgical current.