

AUG 29 1996

510 (k) SUMMARY

Olympus A4907 Lens Cleaning Sheath

Device Name: Olympus A4907 Lens Cleaning Sheath

Common/Usual Name: Lens Cleaning Tube

Classification Name: Endoscope and Accessories
21 CFR 876.1500, Class II

Predicate Devices:

Cook	Lens Cleaner (Unknown)
Wiest	Optic Shaft (Unknown)
DevMed	Lap wash (Unknown)

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Summary Preparation Date: May 8, 1996

Statement of Intended Use:

The A4907 Lens Cleaning Sheath has been specifically designed to be used with the Olympus A4908 Valve and LTF-V OES V Laparo-Thoraco Videoscope to clean of the objective lens surface.

Device Description

The A4907 Lens Cleaning Sheath has been specifically designed for use with the Olympus A4908 Valve and LTF-V OES Laparo-Thoraco Videoscope. It will be included in the standard set of LTF-V Laparo-Thoraco Videoscope and will also be marketed separately.

When connected to the main body of LTF-V videoscope, it offers lens cleaning, irrigation, and suction capabilities to the user during endoscopic procedures. It is substantially equivalent in design, intended use, and method of operation to the "Lens Cleaner" manufactured by Cook, "Optic Shaft" manufactured by Wiest, and "Lap Wash System" manufactured by DevMed Group Inc.

General Safety

When compared with the predicate devices, Olympus A4907 Lens Cleaning Sheath does not incorporate any significant change in intended use, method of operation, material, or design that could affect the safety or effectiveness of the subject device.