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Richard Wolf Medical Instruments Corporation

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**Summary of Safety and Effectiveness**  
**510(K) Summary of Safety and Effectiveness**

**1.0 Classification Name:**

DEC - 2 1996

Endoscope, Flexible

**2.0 Common/Usual Name:**

Flexible Endoscope

**3.0 Trade Name**

Flexible Mini-Fiberscopes

**4.0 Equivalence:**

The submitted devices are equivalent to the following devices already on the market:

Circon ACMI Models AUR-8, AUR-9, AUR-PN  
Karl Storz Model 11274AA  
Olympus Models PF-28, URF-P2

**5.0 Description:**

The flexible mini-fiberscopes are endoscopes with working channels that allow physician control of the tip position and accessory instruments.

**6.0 Intended Use:**

The flexible mini-fiberscopes are intended to be used in various Gastroenterology/Urology Procedures. These uses are:

- 1) Cystoscope - Used to examine the urinary tract, and, using additional accessories, to perform various diagnostic and therapeutic procedures.
- 2) Choledochoscope - Used to examine the bile ducts, and using, additional accessories, to perform various diagnostic and therapeutic procedures.
- 3) Ureteroscope - Used to examine the ureter, and using additional accessories, to perform various diagnostic and therapeutic procedure.
- 4) Nephroscope - Used to examine the kidney, and with additional accessories, to perform various diagnostic and therapeutic accessories.

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**Summary of Safety and Effectiveness (cont.)**

- 5) Uretero-roscope - Used to examine the ureter and kidney, and additional accessories, to perform various diagnostic and therapeutic procedures.

**Accessory Indications for use.**

- 6) Flexible Biopsy Forceps - Used to obtain small biopsies from tissue.
- 7) Flexible Grasping Forceps - For grasping calculi, both renal and biliary.
- 8) Button Electrode - Used for unipolar coagulation.
- 9) Dormia Stone Extractor - Used for grasping and removal of calculi, both renal and biliary.
- 10) Three Pronged Grasper - Used for grasping and removal of calculi, both renal and biliary.

**7.0 Technological Characteristics:**

The only variation of the submitted devices, when compared to existing scopes on the market, is their smaller size.

**8.0 Performance Data:**

Tests were performed to assure: (a) continued flexibility after repeated (2000) flexs (b) ability to withstand repeated (10,000) insertions (c) that no thermal hazard exists, and (d) that the fiberscopes do not present a High Frequency Hazard.

**9.0 Clinical Data:**

No clinical data was obtained.

**10.0 Data Conclusion:**

The flexible mini-fiberscopes provide expected durability, uses biocompatibly safe materials; and when cleaned, disinfected/sterilized as recommended will provide a patient ready instrument.

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