

DEC 23 1996

SUMMARY OF SAFETY AND EFFECTIVENESS

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Common/Usual Name: Endoscopic Accessory

Proprietary Name: CFS-1 Pump System

Classification: CLASS I

Materials:

All materials used to manufacture the Northgate Technologies Inc. CFS-1 Pump System and tubing sets are non-toxic and have been previously used to manufacture other medical devices.

Description:

The CFS-1 Pump System incorporates a peristaltic pump, motor, controller, power supply, and associated sensors and tubing. The product allows continuous flow to an Endoscopic instrument by the constant re-filling of a fluid source container. **The control of flow rates and source pressures remains in the physician's control by the conventional method of raising or lowering the fluid source container.**

Substantial Equivalence:

Northgate's CFS-1 Pump/tubing sets are substantially equivalent in design, materials, and intended use to numerous currently marketed devices. Other manufacturers of similar devices are Biomedical Dynamics, Olympus, Solos, Zimmer, Sun Medical, and Storz.

Intended Use:

The Nortech CFS-1 Pump system shall be used for supplying fluid for general endoscopic procedures.