MAR 12 1996

510(k) Summary: #K960081

Battery Powered Endoscopic Light Source

1) **Name of Submitter:** Mitsubishi Cable America, Inc.

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2) **Name of Device:** Battery Powered Endoscopic Light Source

Proprietary/Trade Name: (Not yet determined)

Common/Usual Name: Battery Powered Light Source

Classification: Class II

Classification Name: Light Source, Incandescent, Diagnostic (78FCQ)

3) **Name of Predicate or Legally Marketed Device:**

The Mitsubishi Battery Powered Endoscopic Light Source is substantially equivalent to the "Xomed-Treace E-Luminator™ II Battery Powered Disposable Endoscope Light Source" that was approved by FDA for marketing on August 24, 1994, under 510(k) No. K932771.

4) **Description of Device:**

The Mitsubishi Battery Powered Endoscopic Light Source is a lightweight, portable, battery powered light source intended for use with diagnostic endoscopes. The light source is powered by one three-volt lithium battery contained within a leakproof case and controlled by a manual on/off switch. Illumination is provided by a 1.7-watt halogen bulb. The unit may be connected by friction-fit to most manufacturers' endoscopes via adaptors (supplied separately) that attach to the endoscope light cable post.

5) **Intended Use of Device:**

The Mitsubishi Battery Powered Endoscopic Light Source is intended for use as a light source for diagnostic endoscopes.

6) **Comparison of Technological Characteristics:**

The Mitsubishi Battery Powered Endoscopic Light Source is substantially equivalent[1] to the predicate or legally marketed Xomed-Treace E-Luminator™ II Battery Powered Disposable Endoscope Light Source. Mitsubishi's device employs the same design considerations and operating principles. However, the Mitsubishi device can be sterilized and its battery can be replaced to allow the device to be reused. Any differences between the Mitsubishi and Xomed-Treace devices do not raise new questions regarding safety or effectiveness. Each device delivers incandescent light to the endoscope to illuminate the target under observation.

[1] The term, "substantially equivalent," is intended to reflect a determination of substantial equivalence under the Federal Food, Drug, and Cosmetic Act, and relates to the fact that the product can be marketed without premarket approval or reclassification. Such a determination is not intended to have any bearing on matters relating to patents.