

K955717

510(k) Summary: #K95 _____

Endoscope Introducer Kit

- 1) **Name of Submitter:** Mitsubishi Cable America, Inc.
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 - 2) **Name of Device:** Endoscope Introducer Kit
Proprietary/Trade Name: (Not yet determined)
Common/Usual Name: Endoscope Introducer Sheath
Classification: Class II
Classification Name: Sheath, For Endoscope (78FED)

 - 3) **Name of Predicate or Legally Marketed Device:**
The Mitsubishi Endoscope Introducer Kit is substantially equivalent to the "Candela Introducer Sheath System" that was approved by FDA for marketing on August 16, 1991, under 510(k) No. K912443.

 - 4) **Description of Device:**
The Mitsubishi Endoscope Introducer Kit consists of an internal dilator (with luer fitting to accommodate a hemostasis valve) contained within an external sheath (with attached hemostasis valve and luer fitting). The dilator may be straight or curved and has a lumen to allow passage of a flexible guidewire.

 - 5) **Intended Use of Device:**
The Mitsubishi Endoscope Introducer Kit is intended to provide an open channel to allow insertion of a small diameter endoscope during laparoscopic choledochoscopy.
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6) **Comparison of Technological Characteristics:**

The Mitsubishi Endoscope Introducer Kit is substantially equivalent¹ to the predicate or legally marketed Candela Introducer Sheath System. Mitsubishi's devices employ the same design considerations, materials of construction and operating principles. The Mitsubishi devices also employ lengths, diameters, and smoothly finished contours similar to those of the predicate devices and can be sterilized. Any differences between the Mitsubishi and Candela devices do not raise new questions regarding safety or effectiveness. None of the devices actively delivers any form of energy to 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.

