

SEP 17 1996

EXHIBIT IX**510(k) SUMMARY**

Kathy Feltrin
Regulatory Affairs

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Common Name: Percutaneous Endoscopic Gastrostomy (P.E.G.)
Feeding Tube
Classification name: Gastroenterology Tube (78 KGC)
Trade Name: None Established

The Domed Percutaneous Endoscopic Gastrostomy (P.E.G.) Feeding Tube is a percutaneously placed gastrostomy feeding device used to administer nutrition directly into the stomach. This device has been designed to be substantially equivalent to the U.S. Endoscopy P.E.G. Systems and the AMT P.R.G. Feeding Tubes.

The device is available in either the guidewire or pullwire method. The domed shaped internal bolster is injection molded onto clear medical grade silicone tubing. The tubing has graduated markings which allows for verification of tube positioning. The internal bolster is also composed of medical grade silicone but which has been pigmented with barium sulfate which provides radiopacity. The internal bolsters' shape allows for ease of passage during placement and is advantages because it permits passage of a jejunostomy tube if jejunal feeding is required.

The Domed P.E.G. Feeding Tube has been developed incorporating all of the safety and effectiveness features of the U.S. Endoscopy P.E.G. Systems and the AMT P.R.G. Feeding Tubes. The device is sold sterile for single use with all the supplies required to perform the procedure.