

510(k) Summary
Gabriel Medical, Incorporated
InfraVision™ Bougie

K 960173

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1. SUBMITTER NAME AND ADDRESS

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2. DEVICE NAME

Proprietary Name: InfraVision™ Bougie, InfraVision™ Esophageal Kit
Common/Usual: Esophageal Dilator, Rectal Dilator
Classification Name: Esophageal and Gastrointestinal Bougie
Urological Bougie

3. PREDICATE DEVICES

BioEnterics Corp. EndoLumina Illuminated Bougie (K934084)
Gabriel Medical Ureteral Illuminator System II(K945088)
InfraVision™ Imaging System(K945297).

4. INTENDED USE

The InfraVision™ Bougie is intended to aid in the identification of the esophagus, rectum, rectosigmoid, other structures, and surgically produced cavities using infrared transillumination during laparoscopy, thoracoscopy, or open procedures.

5. DEVICE DESCRIPTION

The InfraVision™ Bougie is intended to aid in the identification of the esophagus, rectum, rectosigmoid, other structures, and surgically produced cavities using infrared

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transillumination during laparoscopy, thoracoscopy, or open procedures. The indications for use are detailed below:

- a. Infrared transillumination of the esophagus to assist in the identification and location of the esophagus and its surrounding tissues during laparoscopic, thoracoscopic, and open procedures;
- b. Infrared transillumination of the rectum and rectosigmoid to assist in the identification and location of these structures and surrounding tissues during gynecological and colorectal laparoscopic and open procedures; and
- c. Infrared transillumination of other organs or provide transillumination or illumination to other natural or surgically produced cavities.

6. TECHNOLOGICAL CHARACTERISTICS

The InfraVision™ Bougie is a disposable device ranging in diameters from 13 Fr to 60 Fr, all having bougie sheath lengths of 80 cm. The overall length of the InfraVision™ Bougies is 250 cm. The InfraVision™ Bougie has a translucent tip that is either tapered or rounded in shape and varies in length.

7. TESTING

Testing was performed using simulated test tissue to measure heating of tissues using the InfraVision™ Bougie Emitting Fiber and the EndoLumina predicate device . There was significantly less tissue heating observed using the InfraVision™ System dual fiber emitters compared to the EndoLumina energized with a Cabot Medical System 3000 Xenon Videolap Light set to full power.