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510(k) SUMMARY OF SAFETY AND EFFECTIVENESS:

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of the Safe Medical Device Act of 1990 and 21 CFR 807.92.

Substantially Equivalent Device which is legally marketed:

BioEnterics Corporation (BEC) considers the ENDOLUMINA® II Transillumination System to be substantially equivalent in design and use to the ENDOLUMINA® I Illuminated Bougie.

Description of Premarket Notification Device:

The ENDOLUMINA II Transillumination System (EIB II) is a medical device designed to aid in the identification of the esophagus, rectum, and other structures by transillumination during laparoscopy, thoracoscopy, or open procedures. The EIB II consists of a glass fiberoptic bundle inserted into a length of silicone elastomer tubing in a configuration similar to a fiberoptic cable.

Attached to the cable's *proximal end* is a ball-shaped or barb-shaped fitting which allows a clear, flexible, and detachable silicone tip to be attached or removed by means of a "pop-fit" connection. This tip is available in both blunt and tapered configurations. The EIB II is available in sizes ranging from 4 to 60 Fr.

A light source connector/fitting is permanently attached to the *distal end* of the cable and is designed to be inserted into a commercially-available light source. Light generated from the light source is transmitted through the cable's fiberoptic bundle and down into the clear silicone tip, where it is deflected radially to enhance transillumination.

The EIB II is supplied with one (1) cable assembly, which is supplied *nonsterile* and is designed to be *reusable* by the customer. Instructions for methods for cleaning and sterilizing the EIB II cable assembly are provided. The EIB II also contains three (3) detachable tips which are individually packaged in a double pouch system and labeled as *sterile* and for *single use only*. The sterilization method for the tips has been qualified and validated to provide a sterility assurance level (SAL) of 10^{-6} .

Comparison to the Legally Marketed Device (Substantially Equivalent):

In comparison to the ENDOLUMINA Bougie (EIB I), BioEnterics Corporation considers the ENDOLUMINA Bougie II (EIB II) to be substantially equivalent in design, indications, and intended use. Both devices are slender, flexible, and cylindrical instruments for introduction into intact natural channels as well as surgically created pockets. Both devices consist of a glass fiberoptic bundle inserted into a length of silicone elastomer tubing in a configuration similar to a fiberoptic cable. One end of the cable is attached to a clear silicone elastomer tip and the other

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end connects to commercially-available light sources. Materials used to fabricate both devices have been evaluated and have passed requirements for biocompatibility.

The EIB I consists of a clear silicone elastomer tip which is permanently attached to the proximal end of an approximately 25.6 inch long cable. A connector/fitting is attached to the cable's distal end to facilitate connection to a commercially-available light source cable. Like the EIB II cable, the EIB I can be cleaned, sterilized, and reused.

In comparison, the EIB II has a cable which is approximately 96.1 inches long and is designed to connect directly to a commercially available light source. However, when connected to a high intensity light source and left at maximum intensity until the temperature stabilizes, the "heat build-up" or maximum temperature of the tips is not hot enough to cause damage to surrounding tissues. The EIB II is designed to have detachable tips which are packaged, sterilized by a validated cycle, and provided separate from the cable assembly.