K962255

SEP 11 1996

510(k) Summary

Model 2127 Endoscope

General Information

Classifications Class II

Trade Name Clarus Model 2127 MurphyPEN™

Submitted Clarus Medical Systems, Inc.
1000 Boone Avenue North, #100
Minneapolis, Minnesota 55427

Contact: John Vanden Hoek
Director - Research and Development
(612) 525-8400

Substantially Equivalent and Predicate Devices

1. Model 2126 SpinePEN Endoscope by Clarus Medical
   Model 2120 NeuroPEN Endoscope by Clarus Medical
   Model 2125 MurphyScope by Clarus Medical
   Model 2400 InstrumentScope by Clarus Medical
   Model 2240 Otoscope by Clarus Medical
   Model Number C-DFO-1.6-40-Radiscope™ Optical Fiber by Cook Critical Care
   Model S1002 Diaguide by Mitsubishi
   Model SLS Endoscope by Schott

Device Description

The Clarus Model 2127 Endoscopes will be manufactured using medical grade biocompatible materials. The materials to be used are the same as those used in other Clarus Series 2100 Flexible Endoscopes and other Clarus Series Endoscopes. Further, the sizes and configurations of the endoscope are equivalent as well.

The Model 2127 Endoscope is a flexible tubular device with plastic and stainless steel connectors. The optical element of the endoscope consists of a fiber optic image element with a distal lens and fiber light guide. The endoscope also has separate cannulae. Passive deflection allows the physician to move the endoscope's tip through the curved cannula tube during mounting and also allows the physician to bend the endoscope to the desired shape while the endoscope is attached to the cannula. The light and image guides are terminated with standard connectors designed to interface with light cables and video cameras.

The basic design of the Clarus Model 2127 Endoscope is, and materials used are, equivalent to the Clarus Model 2126, Model 2125, Model 2240, and Model 2120 Endoscopes. The diameter of the Endoscope is 1 mm to 2 mm and the working length varies for the different model dash numbers available. The working length for nasolaryngeal procedures requires a cannula of 10.4. The working length for the cannula which would also pass the larynx and into the bronchi would be of 25.0 to 30.0 cm length.

Intended Use

The Clarus Model 2126 SpinePEN is intended for diagnostic accessing and visualizing tissue during cranial sinus, laryngopharyngeal and bronchial procedures. It is not intended for intraoperative or percutaneous use. The endoscope is reusable and is packaged with five disposable cannulae.

Testing

Biocompatibility testing was performed on the materials used in the construction of these endoscopes. All materials passed biocompatibility testing and are suitable for this application.

Physical testing of similar and substantially equivalent endoscopes included: a cleaning validation protocol and study, dimensional inspection, bond strength testing, distal tip temperature, optical clarity, light transmittance, and fluid flow. All testing of the product yielded acceptable results.

Summary of Substantial Equivalence

The Clarus Model 2127 Endoscopes are constructed of the same materials as other Series 2100 Flexible Endoscopes and Models 2126, 2125, 2120, 2400 and 2240, as well as other Clarus products. The sizes and configurations available along with the packaging and sterilization methods are equivalent to Model 2126, 2120, and Model 2125. The Model 2127 will fall within the Clarus 2100 Series of endoscopes as filed under K912089 which is cleared for reuse. Models 2126 and 2240 endoscope as filed under K934432 are also cleared for reuse.

The clinical indications for use are similar to those of the Rapiscope Optical Fiber endoscope by Cook Critical Care, the Diaguide endoscope by Mitsubishi and the Model SLS endoscope by Schott.

Therefore, due to the similarity of materials to other Clarus devices, the test results and the equivalent indications for use of other predicate devices, Clarus believes these products do not raise any new safety or effectiveness issues.