

DEC 24 1996

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510(k) Summary

Model 2121-XXX NeuroPen Endoscopic Shunt Placement Kit

General Information

Classifications Class II

Trade Name Clarus Model 2121-XXX NeuroPEN™ Endoscopic Shunt Placement Kit

Submitter Clarus Medical Systems, Inc.
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Predicate Devices

Model 2120 NeuroPen Endoscope by Clarus Medical
Model 2125 MurphyScope by Clarus Medical
Catalog No. 82-6570 NEUROGUIDE Endoscopic Shunt Placement Kit by J & J

Device Description

The Model 2121-XXX NeuroPEN Endoscopic Shunt Placement Kit contains an endoscope designed and manufactured by Clarus Medical and a FDA cleared shunt.

The Model 2121-XXX NeuroPEN endoscope is manufactured using medical grade biocompatible materials. The design of and materials used are the same as those used in other Clarus Series 2100 and Series 2200 Endoscopes. Further, the sizes and configurations of the endoscope are equivalent as well. The Model 2121-XXX endoscope is a tubular device with molded plastic connectors. The optical element of the endoscope consists of a fiber optic image bundle with a distal lens and a fiber light guide. The endoscope also has a separate fluid irrigation channel. The light and image guides are terminated with standard connectors designed to interface with light cables and video cameras. The fluid irrigation channel is terminated with a standard Luer-Lok™ connector.

Intended Use

The design, materials used and intended use of the Clarus 2121-XXX Endoscope Shunt Placement Kit is substantially equivalent to the Johnson & Johnson #B2-6570 Endoscopic Shunt Placement Kit.

The Clarus Model 2121-XXX NeuroPEN Endoscopic Shunt Placement Kit is intended for endoscopic intraoperative intracranial neurosurgical shunt placement procedures where cerebrospinal fluid (CSF) may be contacted. The endoscope and the shunt are supplied sterile and are intended for single use.

Testing

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

Physical testing of the endoscope included: dimensional inspection, visual examination for workmanship, bond strength testing, optical clarity, light transmittance, distal tip temperature study and fluid flow. All testing of the product yielded acceptable results.

Summary of Substantial Equivalence

The Clarus Model 2121-XXX NeuroPEN Kit endoscopes are constructed of the same materials as other Series 2100 and Series 2200 endoscopes and Models 1100 and 1102 Laser Endoscopic Disc Decompression Kits as well as other Clarus products. The sizes and configurations available along with the packaging and sterilization methods are also equivalent.

The clinical indications for use of the Model 2121-XXX NeuroPEN Kit are equivalent to those of the NEUROGUIDE Endoscopic Shunt Placement Kit marketed by Johnson & Johnson. The sizes and configurations available along with the packaging and sterilization methods are also equivalent.

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