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510(k) Summary of Safety and Effectiveness in Accordance with SMDA of 1990

Aesculap Ventriculoscope System

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Products: Aesculap Ventriculoscope System
Common Names: Ventriculoscope and Accessories

Intended Use

Aesculap's ventriculoscope and associated instruments are designed for visual orientation and therapeutic neurosurgical procedures within the ventricular system, such as vetriculostomies, biopsies and removal of cysts, tumors and other obstructions.

Technological Characteristics

The Ventriculoscope System presented in this submission consists of eleven devices: a working channel, rigid endoscopes, flexible instruments and electrodes. The primary material of construction is stainless steel. The electrodes are coated with a biocompatible fluoropolymer.

Testing

All the products have undergone testing to ensure that the devices work well with each other and are safe and effective. Heat build-up testing was also performed on the rigid scopes.

Sterilization

The ventriculoscope and associated instruments are provided non-sterile and must be sterilized prior to use. The devices may be sterilized by EtO or by pre-vacuum steam sterilization. The ventriculoscope and instruments have been sterilized and validated by both methods to a SAL of 10^{-6}. Validation testing was performed by NAmSA following USP methods.

Substantial Equivalence

Aesculap's Ventriculoscope System shares similar features and function with corresponding devices distributed by:

- Aesculap [Neuroendoscope]
- R. Wolf [Cerebral-Endoskop];
- Neuro-Navigational [Neuroview™ Endoscope]
- Codman's Neurological Rigid Endoscopes, Gaab and Chavantes-Zamorano Neuroendoscopes and the Steerable Endoscope.

All of these neuroendoscopes are intended for visualization and therapeutic procedures during neurological applications. They utilize fiber optics within a outer catheter sheath, and they are similar in dimensions and features. Associated endoscopic instruments available with the Codman Gaab and Chavantes-Zamorano neuroendoscopes are similar in dimensions and use as those in Aesculap's Ventriculoscope System.