

510(k) Summary
Smith & Nephew, Inc., Endoscopy Division,
Images Video System and Hand Instruments

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Endoscopy Division

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Substantial Equivalence

The Smith & Nephew Images Video System components and manual surgical instruments for sinus surgery offered by Smith & Nephew, Inc., Endoscopy Division are substantially equivalent in both design and intended use to sinusscopes, surgical cameras, video components, illumination products and ENT hand instruments offered by Smith & Nephew, Inc., ENT Division.

The Video Components, Surgical Cameras, Illuminators and accessories offered by the above referenced manufacturers mate with the endoscope to allow for visualization during the surgical procedure. The Illuminators, Light Guides and accessories mate to the light post of the endoscope and deliver light to the surgical site.

Manual Surgical Instruments for Sinus Surgery offered by Smith & Nephew, Inc., Endoscopy Division are substantially equivalent in materials, design and intended use to ENT hand instruments offered by Smith & Nephew, Inc., ENT Division.

Predicate Device:

The predicate devices for this submission are the sinusscopes, video components, surgical cameras, illuminators and accessories and ENT surgical hand instruments manufactured and distributed by Smith & Nephew, Inc., ENT Division.

Summary of Device Function:

The Smith & Nephew Images Video System offered by Smith & Nephew, Inc., Endoscopy Division includes the following components:

Smith & Nephew Images Arthroscopes/ENT Endoscopes, Surgical Cameras and various video monitors, video recording devices, image enhancement devices, disk recorders and accessories. The surgical cameras and accessories mate to the endoscope by means of various camera couplers, beamsplitters, and video adapters to allow for visualization during the surgical procedure.

Smith & Nephew Images Xenon Light Sources, Light Guides and accessories are designed to supply light to the surgical site through the endoscope. The light guides mate to the endoscope and light source with instrument specific adapters.

Smith & Nephew manual surgical instruments for sinus surgery are utilized to examine and treat tissues in the nasal cavity and nasal pharynx.

Intended Use of Device:

Smith & Nephew Images Endoscopic Video System and components are indicated for use in diagnostic and operative arthroscopic, laparoscopic and ENT endoscopic procedures to provide illumination and allow visualization of the surgical site.

Smith & Nephew Manual Surgical Instruments for Sinus Surgery are indicated for the endoscopic examination and treatment of the nasal cavity and nasal pharynx.

Comparison of Technological Characteristics of Predicate Devices:

Smith & Nephew Images Arthroscopes/ENT Endoscopes and Manual Surgical Instruments for Sinus Surgery offered by Smith & Nephew, Inc., Endoscopy Division are substantially equivalent to sinusscopes and ENT surgical hand instruments offered by Smith & Nephew, Inc., ENT Division in intended use, materials and technology.

Smith & Nephew Images Surgical Cameras, Video Components, Light Sources and accessories offered by Smith & Nephew, Inc., Endoscopy Division are substantially equivalent in design, materials and function to Smith & Nephew Images devices described in previous premarket notification submissions. All electro-mechanical equipment complies with UL544 and IEC 601-1 requirements for electrical safety of medical devices. The components of the Smith & Nephew Images Video System are substantially equivalent in both design and intended use to surgical cameras, video components, illumination products and accessories offered by Smith & Nephew, Inc. ENT Division.



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