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*Spectra*Science Biopsy Forceps

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Device Name	
Proprietary Name:	SpectraScience Biopsy Forceps
Common Name:	Biopsy Forceps
Classification Name:	Gastroenterology-Urology Biopsy Instruments (21 CFR 876.1075)
Predicate Device	U.S. Endoscopy Group Inc., Disposable Biopsy Forceps Model #00711206
Device Description	The current design of biopsy forceps has not changed during its long course of past clinical utility. The standard hinged design utilizes cup-shaped jaws to bite or pinch off tissue with minimal complications while providing a viable tissue sample. The cup-shaped jaws also serve to hold the biopsy sample within the forceps until the tissue can be transferred to a biopsy container. The proposed SpectraScience biopsy forceps uses the most basic of standard designs in that no teeth or spikes will be employed in the design. The mechanism of action of the SpectraScience design is identical to predicate devices in that the same standard mechanical design, materials and sizes are utilized. Using identical mechanisms of action and materials results in identical clinical performance. The SpectraScience design employs a different technological characteristic. The SpectraScience design incorporates a fiberoptic illumination fiber. The illumination fiber is intended to provide the endoscopist with adjunctive light directed at the tissue biopsy site in addition to the endoscope's light source. In various anatomies under certain circumstances, the endoscope's light angle may not reveal critical structural

contours which should be considered before a biopsy is performed. The intent of the SpectraScience device is to enhance visualization and thus result in more accurate and precise identification and location of the tissue to be sampled.

The employment of an illumination fiber does not change the forceps' mechanism of action, performance, nor biopsy technique when compared to using standard biopsy forceps. The SpectraScience biopsy forceps illuminates automatically once the forceps jaws are opened. No additional movements, techniques, or steps will be required to deliver additional light to the targeted location. The application of adjunctive cold (xenon or equivalent) light will have no adverse effect on tissue. The proposed illumination technology is identical to the illumination provided by the endoscope. The proven biocompatibility, safety and effectiveness, and clinical utility of fiberoptic illumination dates pre 1976 amendment to present. Therefore, the application of adjunctive light via the SpectraScience biopsy forceps does not negatively affect the safety or effectiveness of performing endoscopic biopsy. On the contrary, adjunctive light is intended to enhance the endoscopist's view of the location to be biopsied.

Product Testing

Biocompatibility	Biocompatibility is verified by vendor certifications and vendor biocompatibility testing.
Sterilization	Sterilization methods are standard and defined. Packaging materials are identical to predicate devices.
Mechanical	Mechanical design, mechanisms of action, materials, dimensions, workmanship, operation, light transmittance, and light source connections are identical to predicate devices and therefore substantially equivalent.

Intended Use

The SpectraScience Biopsy Forceps are designed specifically to provide adjunctive illumination while collecting tissue endoscopically for histologic examination. The instruments are intended for endoscopic gastrointestinal and urologic biopsy and should not be used for any purpose other than their intended function.

Conclusion

SpectraScience, Inc., believes that their biopsy forceps are substantially equivalent to the predicate products due to the use of identical design, materials, indications for use and packaging.