

K964553



Innovators In Medical Device Design

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510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and CFR 807.92.

The trade name of the device for which the determination of substantial equivalence is being sought is "MBI Coaxial Illuminated Retinal Pick". The classification name of the device is Illuminator, Fiberoptic, Surgical Field. It is classified as Illuminator, Fiberoptic, Surgical Field - HBI Reg 878.4580. There are no standards applying to it.

The device is equivalent to the MBI Fiberoptic Endo-illuminator K961036 combined with a hand held surgical instrument. It is very similar to the Trek 9801 Light Pipe Pick K875195. The MBI device has the same intended use, illumination of the operating field and/or the use of a manipulating tool and/or use of irrigation or aspiration during ophthalmic surgery, and the same technological characteristics (materials, except for Helioseal" K813015, used and methods of manufacture). The applicant has been manufacturing light pipes (K961036) for Storz Instrument Co. for the past six years and the submitted device has but three small modification to the existing device as follows:

1. The one large fiberoptic filament is replaced with six smaller filaments of the same material.
2. The tool which in the 9801 Trek pick comes from the bottom of the stainless steel tubing now comes from the center of the instrument, and has a lumen that can accomplish aspiration or irrigation during surgery.
3. Where there was no sealant at the distal end of the fibers there is now a small amount of "Helioseal" (K813015) to position and prevent leakage between the fibers and the tool.

Performance is identical to that of the predicate devices. When in use during ophthalmic surgery, part of the device will come into contact with the eye of the patient. The distal end that will contact the patient is a stainless steel tube enclosing a plastic fiber-optic filament whose flat end surface will give off the light needed by the surgeon. A small portion of the stainless steel tube is fashioned into a surgical instrument that extends past the fiberoptic element. All materials are identical to those used in the predicate devices, except for the "Helioseal" as noted. No parts to which color has been added will come in contact with the eye.

The device will be marketed as a non-sterile not non-pyrogenic device.

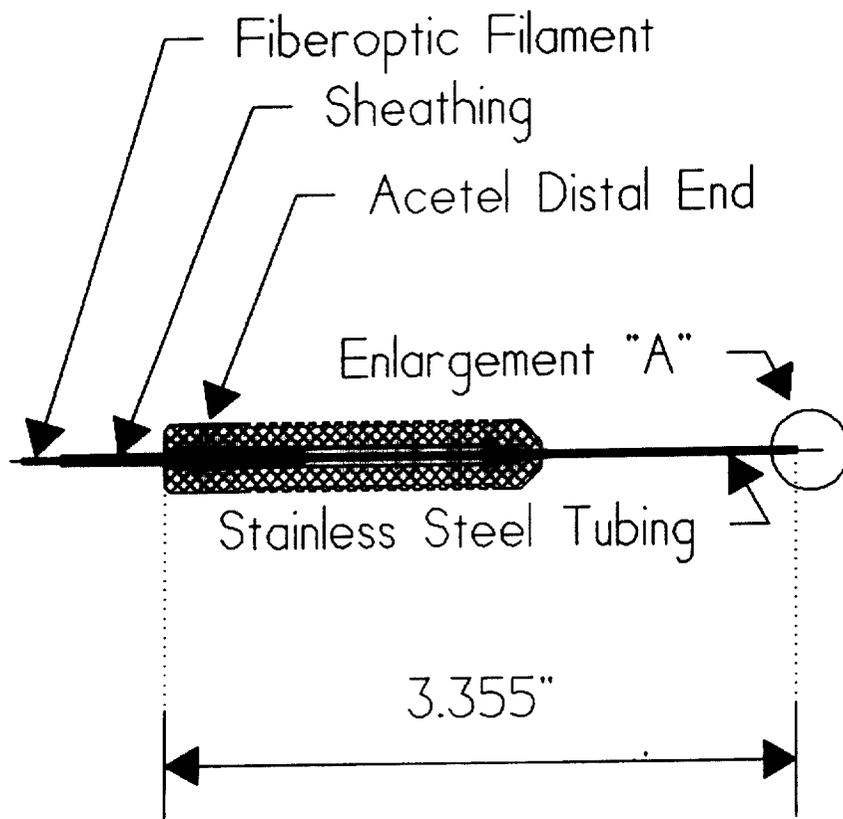
A comparison table of the technological features of this and the predicate device is attached.

Bill Buttermore

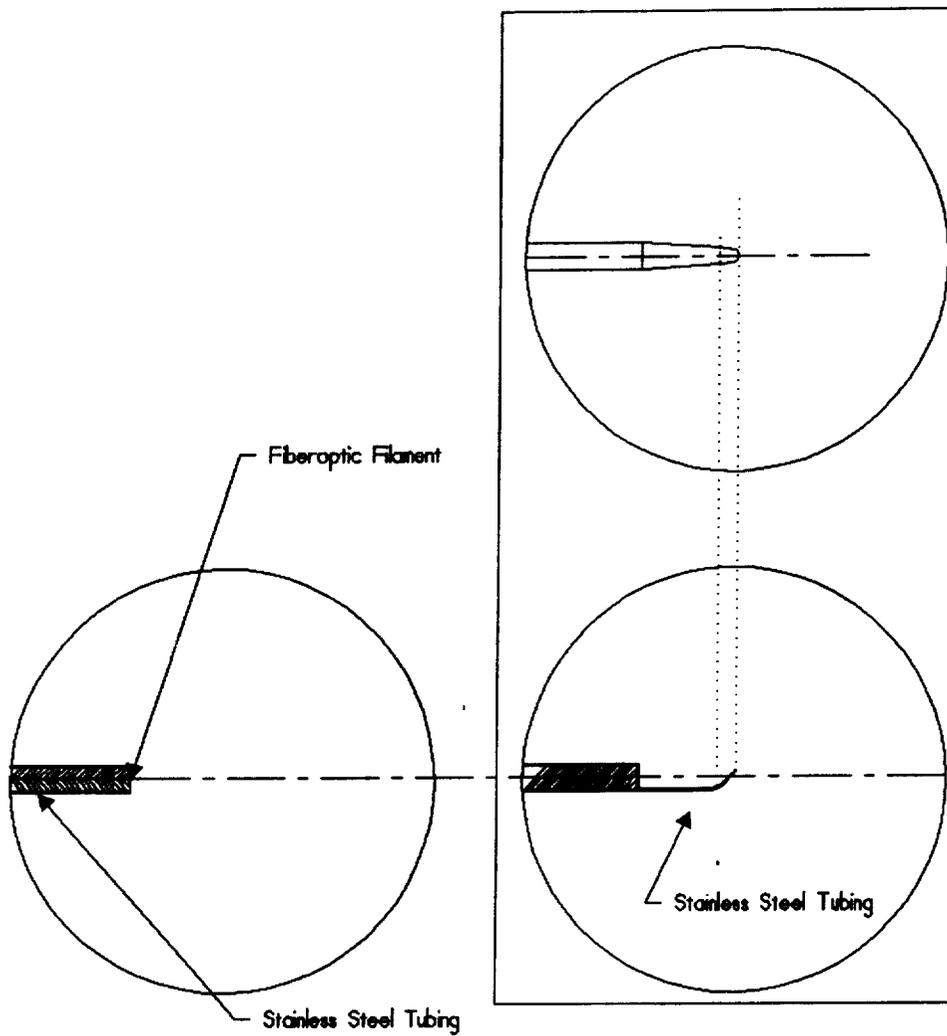
Substantial Equivalence Comparison Chart

	MBI Fiberoptic Endo-illuminator	Hand Held Surgical Instrument	Trek 9502 Light Pipe Pick	Submitted Device: Coaxial Illuminated Retinal Pick
510(k) No.	K961036	Not Applicable	K875195	K964553
Cannula (tube)	Stainless Steel	N/A	Stainless Steel	Stainless Steel
Surgical Tool		Stainless Steel		Stainless Steel
Proximal End	Acetel	N/A	unknown	Acetel
Fiberoptic Filament	Polymethyl methacrylate	N/A	Polymethyl methacrylate	Polymethyl methacrylate
Filament Sheathing	Polytetra fluoroethylene	N/A	unknown	Polytetra fluoroethylene
Distal End	Acetel	N/A	unknown	Acetel
Cannula Protector	Silicone	N/A	Silicone	Silicone
Adhesive proximal end	none	N/A	unknown	none
Adhesive distal end	cyanoacrylate between the fiber and the tubing but at the proximal end of the tubing not entering the eye.	N/A	unknown	cyanoacrylate or "Helioseal" (K813015) between the tubing and the fibers on the proximal tubing end. "Helioseal" at the distal end that enters the eye.
Design of Components	Engineering drawings attached	Instrument design catalog tab "E"	Virtually Identical by actual measurement	Engineering drawings attached

Continued	MBI Fiberoptic Endo-illuminator	Hand Held Surgical Instrument	Trek 9502 Light Pipe Pick	Submitted Device : Coaxial Illuminated Pick
Indications for use	Lighting posterior segment of eye	Tool for manipulation of elements in surgical field or providing aspiration or irrigation within the eye.	Lighting of posterior segment of eye and /or tool for manipulation of elements in eye	Lighting of posterior segment of eye and/or tool for manipulation of elements in eye or aspiration and irrigation within the eye.
Energy delivered	Cool white light	N/A	Cool white light	Cool white light
Biocompatibility	not non-purogenic	N/A	not non-pyrogenic	not non-pyrogenic

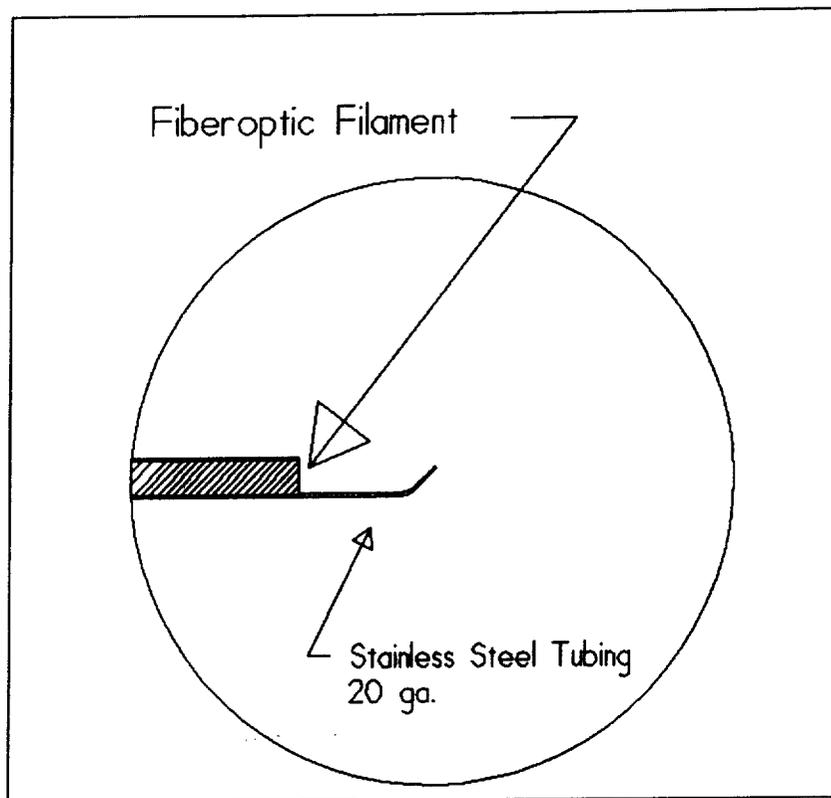


MBI Fiberoptic Endo-illuminator
K961036
Storz Inst. Co. MVS 1011
K896549

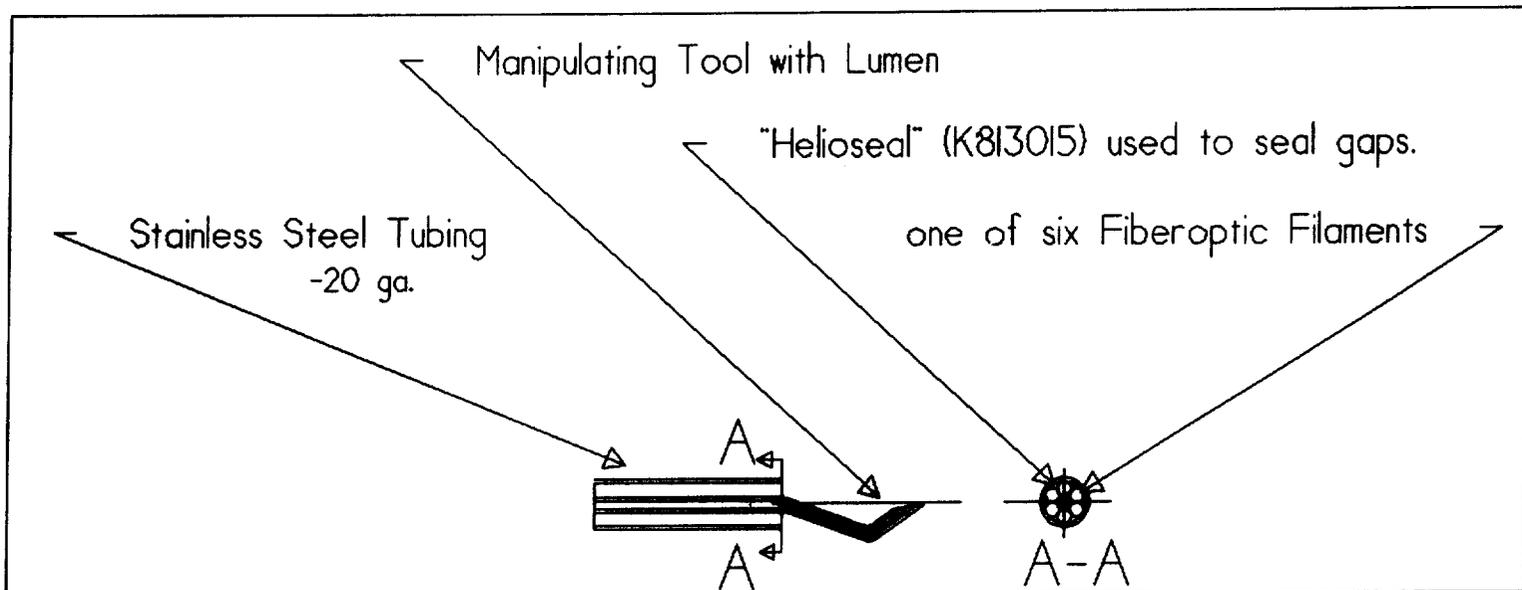


Enlargement "A" - Existing Device
 approved K961036

MBI Illuminated Retinal Pick - not yet
 approved. Identical to Trek 9802
 approved K875195



MBI Illuminated Retinal Pick submitted but not yet approved - identical to Trek 9802 (K875195)



MBI Coaxial Illuminated Retinal Pick - This submission