K964405

MBI INC.

Innovators In Medical Device Design

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HOME OFFICE
14240 Reelfoot Lake Drive
Chesterfield, MO 63017
(314) 576-5005
FAX (314) 576-5006

MANUFACTURING CO.
1707 Madison Avenue
Granite City, IL 62040
(618) 451-2992

William J. Buttermore
President

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Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Boulevard
Rockville, MD 20850

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 Illuminated Retinal Pick". The classification name of the device is Illuminator, Fiberoptic, Surgical Field. It is classified ad 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 virtually identical 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 during ophthalmic surgery, and the same technological characteristics (materials used and methods of manufacture). The applicant has been manufacturing light pipes for Storz Instrument Co. for the past six years and the submitted devise is but a small modification to the existing device.

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 20 ga. 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. Just as in the predicate devices, except for the three plastic constituents which have white color added, all components are natural with no colorants added. Those constituents having white color added are the proximal end plug that is inserted into the light source device which is away from the patient, the sheathing for the fiber optic filament, and the surgeon's grasping point that holds the distal tube that is inserted into the patient's eye during surgery. The colorant is in the plastic material of which the components are made. No constituent to which color is added will come into contact with the patient. There are no changes from the color additives used in the predicate devices.

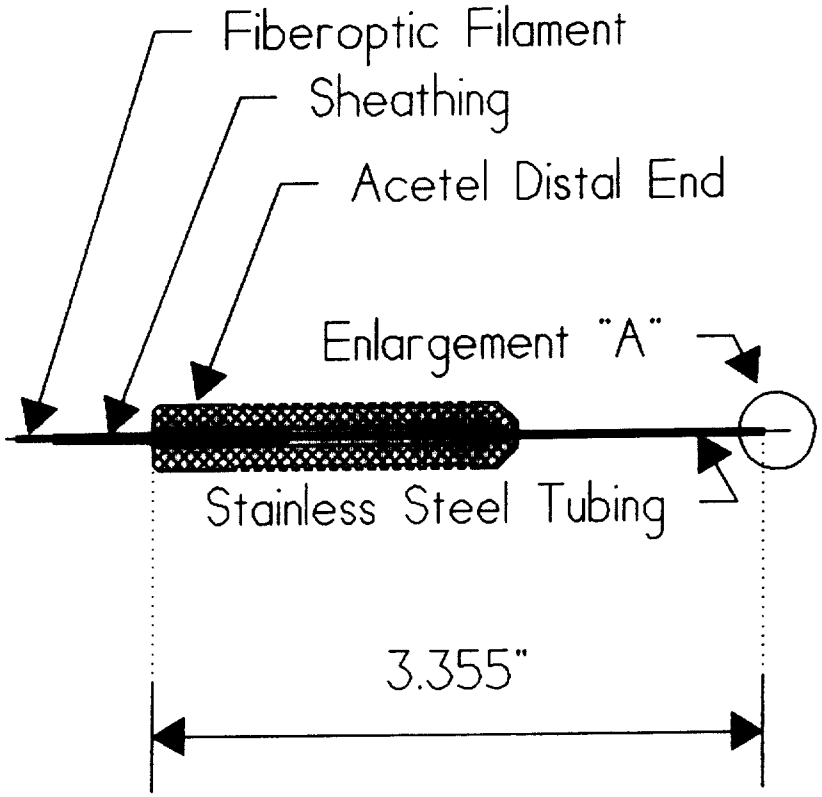
The device will be marketed as a non-sterile not non-pyrogenic device.

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

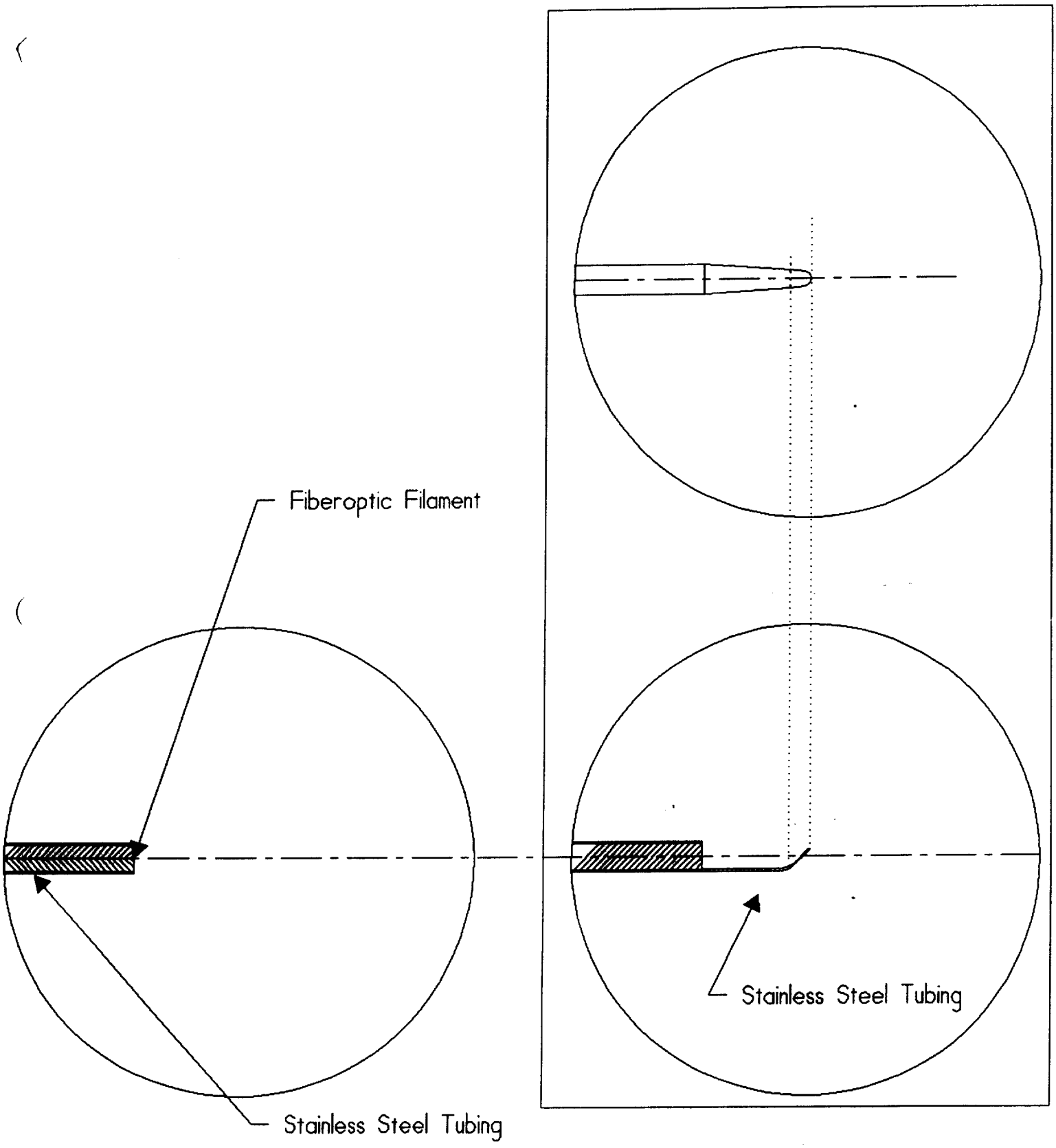
Bill Buttermore

Substantial Equivalence Comparison Chart

	MBI Fiberoptic Endo-illuminator	Hand Held Surgical Instrument	Trek 9502 Light PipePick	Submitted Device
510(k) No.	K961036	Not Applicable	K875195	K964405
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
Filamnet 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	N/A	unknown	cyanoacrylate
Design of Components	Engineering drawings attached	Instrument design catalog tab "E"	Virtually Identical by actual measurement	Engineering drawings attached
Indications for use	Lighting posterior segment of eye	Tool for manipulation of elements in surgical field	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
Energy delivered	Cool white light	N/A	Cool white light	Cool white light
Biocompat-ability	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

Submitted Device
MBI Illuminated Retinal Pick