MBI INC.

JUL 15 1996

Innovators In Medical Device Design

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K961036

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March 8, 1996

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 Fiberoptic Endo-Illuminator". 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 identical to the Storz, MVS Disposable Fiberoptic Lightpipe marketed as a class II post-amendment device by Storz Ophthalmics, Inc. under 510(k) marketing clearance issued by FDA as document control number K854587. The MBI device has the same intended use (illumination of the operating field during ophthalmic surgery) and the same technological characteristics (materials used and methods of manufacture). The applicant has been functioning as a captive manufacturing site producing the predicate device for Storz and now intends to produce and sell to other customers the same device it has been manufacturing for Storz.

Performance is identical to that of the predicate device. 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. All materials are identical to those used in the predicate device. Just as in the predicate device, except for 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 colorant is added will come into contact with the patient. There are no changes from the color additives used in the predicate device.

The device will be marketed as a single-use, sterile device. As with the predicate device, sterility will be obtained by packaging the device in a clean, sealed envelope having a clear plastic window as one side and gas-permeable non-woven plastic fabric (Tyvek) as the other side. In a process identical to that used for the predicate device, sealed envelopes containing the device will be sterilized by ethylene oxide gas which will penetrate the gas-permeable non-woven plastic fabric killing all pathogens on the device. Maximum residual levels of ethylene oxide, ethylene chlorohydrin, and ethylene glycol on the device are 250 PPM, 250 PPM, and 5000 PPM respectively. Successful sterilization will be confirmed by culturing spoor strips embedded in the lot to be sterilized. The device will meet sterility assurance level 10^6. The constituents of the envelope are impenetrable by pathogens ensuring that sterility is maintained as long as package integrity is not compromised. The device is not considered non-pyrogenic.

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