K960522

JUL 19 1996

510(k) Summary
IRIS Medical Instruments, Inc.
DioPexy Probe

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Date Prepared: January 15,1996

Name of Device and Name/Address of Sponsor

DioPexy Probe

IRIS Medical Instruments, Inc.
340 Pioneer Way
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Classification Name

Ophthalmic Laser (Accessory)
CFR Section: 886.4390
Product Code: 86 HQF

Predicate Devices

The IRIS DioPexy Probe for transscleral retinal photocoagulation (TSRPC) is substantially equivalent to four predicate devices currently marketed: (1) the MIRA MD-1000 Microdiathermy System (pre-amendment), (2) the CooperSurgical Frigitronics CE-2000 Ophthalmic Cryosurgical System (K872362, K891282), (3) the IRIS Medical Laser Indirect Ophthalmoscope delivery device (K903288), and (4) the IRIS Medical G-Probe (K915236).

Intended Use

The intended use of this device is transscleral retinal photocoagulation (TSRPC) for retinopexy.

Technological Characteristics and Substantial Equivalence

The DioPexy Probe enables the ophthalmologist to produce chorioretinal adhesions during retinal detachment surgery using delivery of transscleral infrared laser for retinopexy. Retinal detachments develop when a full thickness break in the retina allows vitreous fluid to dissect beneath the sensory retina causing it to separate from the retinal pigment epithelium (RPE)/choroid. To avoid progression to severe visual loss, a surgical procedure is necessary to reattach the retina. The principles of retinal detachment repair include retinopexy. Retinopexy is used to provide a seal around all retinal breaks to prevent further leakage of vitreous fluid into the subretinal space. Retinopexy creates an adhesion between the sensory retina and the RPE/choroid. This is stimulated by the post treatment inflammatory reaction at the level of the RPE/choroid and results in a chorioretinal scar. Current sources of energy used for retinopexy are heat (diathermy and laser) or freezing (cryotherapy).

The MIRA utilizes diathermy for retinopexy. Diathermy has been used for transscleral retinopexy for over 60 years. When used, a diathermy probe is placed on the scleral surface of the eye and heat generated at the tip of the probe is delivered transsclerally to the inside of the eye to the retina/choroid. Diathermy usually requires scleral dissection to minimize scleral damage caused by the heat conduction. The physician determines when sufficient energy is delivered by either observing the burn develop on the retina with a diagnostic indirect ophthalmoscope or by observing an external scleral reaction.

The Frigitronics utilizes cryotherapy for retinopexy. Cryotherapy is delivered transsclerally and was introduced in 1964. When used, a cryoprobe is placed on the surface of the sclera, the sclera is depressed, and cold generated at the tip of the probe creates an ice ball which conducts across the sclera. The physician observes the extent of ice ball progression inside the eye with a diagnostic indirect ophthalmoscope and when sufficient terminates energy delivery.

The IRIS Medical Laser Indirect Ophthalmoscope utilizes 810 nm diode laser photocoagulation for retinopexy. Diode laser

photocoagulation delivered transpupillary has been used since 1989 for retinopexy. When used, the LIO is placed on the physician's head and with the aid of a hand-held indirect lens is used to observe the treatment site. Only breaks which can be viewed directly, with or without the aid of scleral depression, can be treated. When the target is illuminated with the pilot/aiming beam, the physician activates the footswitch and delivers laser energy.

Transscleral application of diode laser has been shown to reduce intraocular pressure in the treatment of glaucoma using the IRIS Medical G-Probe (K915236) through transscleral cyclophotocoagulation (TSCPC). Transscleral photocoagulation of the sub-surface structures can be accomplished by placing a diode laser probe on the surface of the eye and allowing the infrared laser energy to be absorbed by the deep pigmented tissues. Typical laser parameters for TSCPC are 2000 milliseconds duration and 1750 milliwatts of power.

The DioPexy Probe is intended to be used to perform transscleral retinal photocoagulation (TSRPC) in retinopexy procedures to accomplish retinal detachment repair. When using the DioPexy Probe the retinal treatment site is always under direct observation by the treating physician using an indirect ophthalmoscope. The prism tip of the DioPexy Probe is placed on the outer surface of the sclera and the sclera is depressed. A low power visible pilot/aiming beam is projected transsclerally onto the retina. This visible aiming beam can be observed by the physician on the retina during treatment. Size and intensity of the burn can be monitored and titrated with the laser footswitch. The extent of the laser lesion depends upon the energy delivered to the treatment site. Typical laser parameters for TSRPC are 2000 milliseconds duration and 1100 milliwatts of power. When longer duration burns and lower powers are used, burn development is slower. Chorioretinal adhesion also occurs without visible retinal uptake, as with cryotherapy in bullous retinal detachments.

Device Description

The IRIS DioPexy Probe is a multiple-use fiber optic laser delivery device with integral optics, which terminates with a contact prism tip. It must be directly connected to a compatible IRIS OcuLight SL or SLx (810 nm-infrared) Photocoagulator. The prism tip is designed to deflect laser energy 90° from the axis of the shaft and be simultaneously act as a scleral depressor. The fiber optic cable is 3

meters (10 feet). The DioPexy Probe is shipped from the factory non-sterile in a hard plastic container. The device can be sterilized between each use in this container using Ethylene Oxide (EtO) gas in accordance with the user instructions.