

510-k Summary

MAR 17 1997

Pursuant to 21 CFR 807.92 the following summary is submitted.

1. Submitter's name-

Carl Zeiss, Inc.
1 Zeiss Drive
Thornwood, NY 10594
(914) 681-7761
Contact Person-Kenneth M. Nicoll
April 4, 1996

2. Zeiss CPC Probe
Laser Probe

3. We are claiming substantial equivalence to the Iris Medical G-Probe,
K 915236.

4. The Zeiss CPC Probe is a laser delivery system designed for use with the Visulas Diode II laser from Carl Zeiss. When used in tandem they form an ophthalmic laser treatment device. The CPC Probe is used to reduce the intraocular pressure associated with the eye disease Glaucoma. The contact probe is applied with slight pressure to the sclera and located approximately 1.5 mm behind the limbus. This method significantly increases the transmission of the sclera and also reduces the scattering of the laser beam. The power is adjusted and increased successively until the proper effect is heard. The power is then reduced and remaining coagulations can be performed if needed.

5. This device will be used in the same manner as the device mentioned above and will permit the Zeiss Visulas Diode II to be further utilized as a therapeutic ophthalmic laser. It incorporates the same intended uses as the Iris Medical G Probe and specifically is recommended for treating the following eye disease: Glaucoma.

6. The Zeiss CPC Probe is substantially equivalent to the Iris Medical G Probe in that both are used to permit the individual companies laser to deliver impulses that photocoagulate the ciliary body of the eye in patients that are diagnosed with Glaucoma, thereby reducing the patient's intraocular pressure which slows the progress of the disease. The only differences between the two delivery units are: The approximate amount of times the contact tips can be sterilized, the material the tips are made of and slight differences in the power range.