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2. SUMMARY OF SAFETY AND EFFECTIVENESS

SUMMARY OF SAFETY AND EFFECTIVENESS
LASERSONICS Nd:YAG CYLINDRICALLY DIFFUSING
STERILE DISPOSABLE FIBER

REGULATORY AUTHORITY:

Safe Medical Devices Act of 1990, 21 CFR 807.92

COMPANY NAME/CONTACT:

Alan Curtis,
Director Regulatory Affairs/Quality Assurance
Heraeus Surgical, Inc.
575 Cottonwood Drive
Milpitas, CA 95035-7434
Phone: (408) 954-4000
FAX: (408) 954-4326

DEVICE TRADE NAME:

LaserSonics Nd:YAG Cylindrically Diffusing Sterile Disposable Fiber

DEVICE COMMON NAME:

Cylindrically Diffusing Fiber

Note: *LaserSonics is a division of Heraeus Surgical, Inc., located at the same address.*

SUMMARY OF SAFETY AND EFFECTIVENESS,
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DEVICE CLASSIFICATION:

To the best of our knowledge, laser fiberoptic delivery systems have not been classified by the FDA. The Nd:YAG laser systems on which the sterile disposable fibers are intended for use have been classified as Class II (79 GEX) Medical Devices by the OB/GYN, General, Plastic Surgery and ENT Device Advisory Panels.

PERFORMANCE STANDARDS:

Heraeus Surgical is unaware of any specific standards for laser fiberoptic delivery systems. The laser systems manufactured by Heraeus Surgical comply with 21 CFR 1040.10 and 1040.11, FDA regulations for medical laser products, as applicable.

INDICATIONS FOR USE STATEMENT:

The Cylindrically Diffusing Fiber is intended for soft tissue contact and coagulation for all cleared LaserSonics Nd:YAG soft tissue applications.

DEVICE DESCRIPTION-DIFFUSING MATERIAL

COMPARISON WITH PREDICATE DEVICE:

In the opinion of Heraeus Surgical, the Cylindrically Diffusing Fiber is equivalent to the Dornier ThermaFocus 360°™ Fiber. These devices are in all aspects equivalent.

The risks and benefits of the Cylindrically Diffusing Fiber are comparable to the predicate device when used for similar clinical applications.

Since the Cylindrically Diffusing Fiber is substantially equivalent with respect to indication for use, materials, method of operation and physical construction to the predicate device, we believe it clearly meets the requirements for substantial equivalence according to Section 510(k) guidelines. Safety and effectiveness are reasonable assured, therefore justifying 510(k) clearance.