

MAR 18 1997

**SUMMARY OF SAFETY AND EFFECTIVENESS**

**CYBERSCAN DEVICE SYSTEM**

K970017

**REGULATORY AUTHORITY:**

Safe Medical Devices Act of 1990, 21 CFR 807.92

**COMPANY NAME/CONTACT:**

Nidek Incorporated  
47651 Westinghouse Drive  
Fremont, CA. 94539-7474  
Phone: (510)226-5700  
(800) 223-9044  
Fax: (510) 2265750

**DEVICE TRADE NAME**

CyberScan Device

**DEVICE COMMON NAME**

Scanning Laser Delivery System

**DEVICE CLASSIFICATION:**

CO<sub>2</sub> laser systems have been classified as Class II (79 GEX) medical devices by the OB/GYN, General, Plastic Surgery and ENT Device Advisory Panels. To the best of our knowledge, scanning laser delivery systems have not been classified.

**PERFORMANCE STANDARDS:**

The ParaScan Dosimeter Device complies with 21 CFR 1040.10 and 1040.11, FDA regulations for medical laser products, as applicable.

**INDICATIONS FOR USE STATEMENT**

The CyberScan Device is intended for use for all cleared Heraeus LaserSonics CO<sub>2</sub> soft tissue surgical applications.(K955734)

**COMPARISON WITH PREDICATE DEVICE:**

The CyberScan Device is substantially equivalent to the ParaScan Dosimeter Device manufactured by Heraeus Surgical.(K955734)

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

Since the CyberScan Device 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.