

SEP 3 1996

K962242

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510(k) Summary

Submitter: Clinicon Incorporated

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Contact person: Alan Bunting

Date prepared: June 6, 1996

Trade name: SureScan

Common name: Laser Accessory

Classification name: Class II

Substantial equivalence claimed to:

1. Lasersonics Parascan - 510(k) number - K955734 ✓
2. Coherent Computerized Pattern Generator

Description:

SureScan converts any CO₂ laser, pulsed or CW, into a sophisticated aesthetic surgery laser system for performing a wide variety of laser procedures. It comes equipped with six different patterns in 26 different sizes. It automatically adjusts the scan speed to ensure uniform laser ablation which eliminates charring and thermal damage. The collimated beam ensures constant power density and tissue removal at any working distance. The SureScan has an adjustable spot overlap density for more precision and control. The Scan outline and size are clearly displayed on the tissue, allowing precise placement of the laser energy and subsequent scan shapes.

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Intended use:

SureScan may be used for a variety of soft tissue ablation procedures where precise removal is required to minimize damage to adjacent or underlying tissue layers. SureScan employs a microprocessor controlled, mirror system for scanning the laser beam. Using advanced software control, SureScan juxtaposes laser beam spots with precisely controlled amounts of spatial overlap and time between overlap spots. Highly controlled tissue ablation is achieved with minimal thermal injury. The microprocessor controlled fail-safe system eliminates potential hazards because the operation is controlled via an existing laser footswitch, so there is no interference with the internal electronics or workings of the laser. SureScan allows for realignment of a laser beam due to an out of calibration articulated arm. As a result, the physician is always assured of optimum beam quality and mode as it exits the SureScan Device. If the beam characteristics of the laser do not meet the control standards of the SureScan system, an audible warning is provided to the operator and the laser footswitch rendered inoperative.

Summary of technological characteristics:

SureScan adjusts scan speed of the laser beam over tissue according to the specifications of the laser to ensure uniform ablation. Conventional spiral scanners use constant velocity mirror rotation to scan the laser beam in an outward spiraling circular pattern. This results in deeper ablation at the center if laser power is held constant during the scan cycle and has the potential for scarring and or hyperpigmentation.

Different sized squares, rectangles, ellipses, triangles, hexagons, parallelograms and lines may be selected and automatically ablated in a single scan cycle. The results allow for more predictable and controlled tissue effect to optimize treatment results.