

K964074

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**510(k) Summary  
IRIDEX Corporation  
DioLite™ 532**

**Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared**

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**Name of Device and Name/Address of Sponsor**

DioLite™ 532

IRIDEX Corporation  
340 Pioneer Way  
Mountain View, CA 94041

**Classification Name**

Laser Instrument, Surgical, Powered  
CFR Section: 878.4810  
Product Code: 79 GEX

**Predicate Devices**

The DioLite 532 Laser System is substantially equivalent to other currently legally marketed laser devices including the Continuum Biomedical, Inc., CB Diode/532 Laser System (K954905), the Laserscope, Aura Laser System (K951034), and the Innovative Health Concepts, Inc., Vasculase Copper Vapor Laser System (K883541, K903883).

**Intended Use**

The DioLite 532 is a semiconductor-based laser system which delivers 532 nm laser light intended to be used for the photocoagulation of vascular and pigmented skin lesions.

## **Technological Characteristics and Substantial Equivalence**

The DioLite 532 is a semiconductor-based laser system which delivers 532 nm laser light. The DioLite 532 uses infrared (808 nm) semiconductor diode laser light as the primary source of energy which is then wavelength converted to visible green 532 nm laser light for delivery to the patient and treatment. A second visible red (630-650 nm) semiconductor diode laser is used for aiming.

The DioLite 532 is substantially equivalent to other currently legally marketed dermatology laser devices including the Continuum Biomedical, Inc., CB Diode/532 Laser System (K954905), the Laserscope, Aura Laser System (K951034), and the Innovative Health Concepts, Inc., Vasculase Copper Vapor Laser System (K883541, K903883). All of these predicate devices are indicated to be used for the photocoagulation of vascular and pigmented skin lesions.

The Continuum Biomedical, Inc., CB Diode/532 Laser System uses infrared (808 nm) semiconductor diode laser light as the primary source of energy which is then wavelength converted to visible green 532 nm laser light for delivery to the patient and treatment. The CB Diode/532 Laser System delivers the same wavelength, equivalent average power, pulses of equivalent duration, and treatment spots of equivalent diameter to the DioLite 532.

The Laserscope, Aura Laser System uses arc lamps as the primary energy source to optically pump a Nd:YAG laser rod, the output of which is wavelength converted to visible green 532 nm laser light for delivery to the patient and treatment. The Aura Laser System delivers the same wavelength, similar average power, pulses of equivalent duration, and treatment spots of equivalent diameter to the DioLite 532.

The Innovative Health Concepts, Inc., Vasculase Copper Vapor Laser System uses electrical energy to excite a metal vapor discharge to produce yellow 578 nm and green 511 nm laser light for delivery to the patient and treatment. The Vasculase Copper Vapor Laser System delivers similar wavelengths, similar average power, pulses of similar duration, and treatment spots of similar diameter to the DioLite 532.

## **Device Description**

The DioLite 532 is a semiconductor-based dermatology laser system which delivers 532 nm laser light. The system delivers up to 3 Watts of power, in pulses of 1 to 100 milliseconds duration, at repetition rates up to 15 Hz, into treatment spots of 200 to 1400 microns diameter.