

K961748

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510(k) Summary

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Device Trade Name: Medlite\Erbium Laser System

Common Name: Dermatology laser system

Classification Name: Instrument, surgical, powered, laser  
79-GEX  
21 CFR 878.48

Equivalent Device: SEO Medical TriLase 2940 Erbium Laser System (K954013)

Device Description: The Medlite\Erbium Laser is an erbium laser producing laser emissions at 2.94 $\mu$ . The laser consists of three interconnected sections: the power supply, the water cooling system and the optical bench. At 5 pulses per second and a pulse energy of 2 Joules, the average power from the laser is 10 watts.

Intended Use: For use in dermatology for the incision, excision, ablation, vaporization and hemostasis of soft tissue.

Comparison: The TriLase 2940 Erbium Laser has the ability to deliver laser energy at 2.94 microns, maximum power of 5 watts at repetition rates of up to 20 pulses per second. These characteristics are very similar to the Medlite\Erbium Laser System.

Nonclinical Performance Data: none

Clinical Performance Data: none

Conclusion: The Medlite\Erbium Laser System is substantially equivalent to other existing surgical laser systems in commercial distribution for dermatology treatments such as skin resurfacing and dermabrasion.

Additional Information: None requested at this time.