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K 963340

510(k) Summary

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Device Trade Name: Medlite™ Nd:YAG Laser System: New Dye Accessory Handpiece

Common Name: Dermatology laser system

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

Equivalent Device: Medlite™ Nd:YAG Laser System (K955131, K952636, K940607,
K940636, K922935, K922577, K915497)

Device Description: The new Dye Accessory Handpiece for the Medlite™ Nd:YAG Laser System is consists of four primary parts: the handpiece which contains a short optical cavity and focusing optics, the plastic dye module, the commercial power meter and appropriate laser safety goggles.

Intended Use: For use in dermatology for the removal of tattoos and the treatment of vascular and pigmented lesions.

Comparison: The new Dye Accessory Handpiece allows the Medlite™ Nd:YAG Laser System to deliver slightly altered wavelengths for increased efficiency in treating tattoos, vascular and pigmented lesions.

Nonclinical Performance Data: none

Clinical Performance Data: none

Conclusion: The Medlite™ Nd:YAG Laser System is substantially equivalent to other existing surgical laser systems in commercial distribution for the treatment of tattoos, vascular and pigmented lesions.

Additional Information: None requested at this time.