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K961006

510(k) Summary

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Device Trade Name: Medlite\755™ Alexandrite Laser System

Common Name: Dermatology laser system

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

Equivalent Device: PhotoGenicaT¹⁰ Laser (Cynosure) K950684

Device Description: The Medlite\755 Alexandrite Laser is a flashlamp excited Q-switched solid state laser producing a broadband wavelength of 755 ±25nm. Medlite\755™ Alexandrite Laser System is currently marketed under K935631, SE date 08/23/94, for tattoo removal.

Intended Use: Treatment of pigmented lesions.

Comparison: Cynosure's PhotoGenica T¹⁰ Laser emits light at 752nm in a flashlamp-excited pulsed mode. Indications for use, target, chromophore, delivery system, spot size, mode of operation, exposure duration, average laser power, energy to lesion aiming beam, laser wavelength, etc. for the Medlite\755 Alexandrite Laser System are all within the parameters currently in use by other systems which have been previously found to be substantially equivalent.

Nonclinical Performance Data: none

Clinical Performance Data: none

Conclusion: The Medlite\755 Alexandrite Laser System is substantially equivalent to other existing surgical laser systems in commercial distribution for the treatment of pigmented lesions.

Additional Information: None requested at this time.