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510(k) SUMMARY

MEHL QD RUBY LASER SYSTEM FOR HAIR REMOVAL

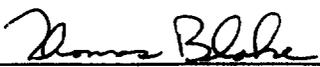
The Mehl QD Ruby Laser is a laser instrument used in medical practice for the removal of unwanted body and facial hair. Reviewed by the General and Plastic Surgery Device Classification Panel, medical lasers are assigned the Product Code 79GEX and are regulated under 21 CFR 878.4810 as Class II (Performance Standards) devices.

From an operational standpoint the Mehl QD Ruby Laser is substantially equivalent to any number of laser devices, including the Spectrum Model RD-1200 (K910422), used in Dermatology practice. They produce the same wavelength, deliver the same energies to the skin, and are constructed of similar components.

With respect to its patented procedure for removing hair, the Mehl QD Ruby Laser is substantially equivalent to the ThermoLase LT-100 Q-Switched Nd:YAG laser (K950019) in that,

1. Both types of lasers are widely used for dermatological applications;
2. Each is based upon the same technological characteristics;
3. Both employ the same principle of selective photothermolysis for depilation, although the Mehl laser achieves the same or better effect without the use of the carbon-based lotion and pretreatment waxing required by the ThermoLase system;
4. The ability of the ruby laser to remove hair was measured in three clinical studies. In one of these studies, 38.4% of the sites receiving only one treatment showed a 100% reduction in hair density after an average of 72 days.

In all three studies, no safety issues were identified. No scarring or purpuric reactions were observed, though skin discoloration (hyper- and hypopigmentation) was noted, but was seen to resolve within a few months.



Thomas Blake, R.Ph.
REGULATORY STRATEGIST

5/29/96
Date