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ATTACHMENT A

510(k) SUMMARY

MCL 29 DERMABLATE ERBIUM LASER SYSTEM

This 510(k) summary of safety and effectiveness for the MCL 29 Dermablade erbium laser system is submitted in accordance with the requirements of SMDA 1990 and follows Office of Device Evaluation guidance concerning the organization and content of a 510(k) summary.

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Preparation Date: October 3, 1996
(of the Summary)

Device Trade Name: MCL 29 Dermablade Er:YAG Laser System

Common Name: Erbium: Yttrium, Aluminum; Garnet (Er:YAG)
Laser System

Classification Name: Laser surgical instrument for use in
general and plastic surgery and in
dermatology (see: 21 CFR 878.4810).
Product Code: GEX.

Legally marketed predicate devices: Schwartz Electro-Optics, Inc. TriLase 2940
Erbium Laser;
Continuum Biomed, Inc., Multilite Erbium
Laser System

Description of the Device: The MCL 29 Dermablade laser is an
erbium:YAG of power at 2.94um. See below
for additional specifications.

Intended Use of the MCL 29 Dermablade laser: The MCL 29 Dermablade laser is intended for
coagulation, vaporization, ablation, or
cutting of soft tissue (skin) in dermatol-
ogy, plastic surgery (including aesthetic

organs and glands. Surgical specialties include *dermatology, plastic surgery, general surgery, urology, gynecology, pulmonary surgery, gastroenterology, ENT, thoracic surgery, oral & maxillofacial surgery, ophthalmology, and podiatry.* (**emphasis added**)

Multilite Laser: The Multilite laser information includes "Cosmetic laser surgery...[is] primarily restricted to applications in dermatology, plastic surgery, and aesthetic surgery." (**emphasis added**)

Performance Data: None. The specifications and intended uses of the MCL 29 Dermablate laser are the same or very similar to those of the claimed predicate devices. There are no significant differences between the devices under conditions of intended use.

Because of this, performance data were not required.

CONCLUSION: Based on the foregoing and other information in this application, AESCULAP-MEDITEC believes that the MCL 29 Dermablate laser is substantially equivalent to legally marketed predicate devices, i.e., the Schwartz Electro-Optics, Inc. TriLase 2940 erbium laser (K954013) and the Continuum Biomed, Inc. Multilite erbium laser system (K961748).