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1. 510(K) SUMMARY- SUMMARY OF SAFETY AND EFFECTIVENESS

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Name of device: PhotoDerm[®] PL

Predicate devices: Candela PLDL-1
Laserscope 532nm KTP
Redfield IR Coagulator

Description of device: PhotoDerm[®] PL is an electro optic medical device designed for effective photothermal treatment of benign pigmented lesions and tattoos non-invasively.

Summary:

Pursuant to section 513(I) of the Safe Medical Devices Act of 1990, ESC Medical Systems has elected to include in this premarket notification a Summary of Safety and Effectiveness upon which we believe a substantial equivalence determination for the PhotoDerm[®] PL can be based.

It is our understanding that there are presently no FDA regulations describing the form and content of such Summaries. With this in mind, ESC Medical Systems has tried to anticipate what information may be of particular interest to the agency regarding safety and effectiveness of the PhotoDerm[®] PL.

Intended use:

The PhotoDerm[®] PL is a system intended for the treatment of benign pigmented lesions and tattoos. The Candela PLDL-1, Laserscope 532 KTP, and the Redfield IR Coagulator have been classified as Class II devices and were reviewed by the General and Plastic Surgery Devices Panel. ESC Medical Systems claims that the PhotoDerm[®] PL is substantially equivalent to these devices.

Comparing technical characteristics:

Both a technical comparison and clinical trials were performed by ESC Medical Systems to establish this equivalence:

ESC has performed a detailed comparison of the technical specifications of these predicate devices and the PhotoDerm[®] PL. The results have documented that the system specifications of the PhotoDerm[®] PL are well within the range of the technical specifications of the predicate devices.

A theoretical study was conducted to establish the temperature distribution resulting from a treatment of pigmented lesions and tattoos by the PhotoDerm[®] PL. The temperatures reached by a wide range of lesions, typical to benign pigmented lesions exposed to the light energy of the PhotoDerm[®] PL, was evaluated. It is the view of ESC Medical Systems that this analysis demonstrates that the PhotoDerm[®] PL is an effective treatment modality of benign pigmented lesions and tattoos, and is safe in minimizing the adverse effects in the surrounding tissues.

Performance:

In addition, ESC Medical Systems has also conducted a multi-center clinical study in which benign pigmented lesions were treated by the PhotoDerm[®] PL. This study was analyzed and the clearance rates and rate of occurrence of adverse effects of the PhotoDerm[®] PL were established. This data was compared to published data on the clearance rate and adverse effects of predicate devices. It is ESC's opinion that this comparison demonstrates that the PhotoDerm[®] PL is as safe and as effective as predicate devices in the treatment of benign pigmented lesions.

No performance standards applicable to the PhotoDerm[®] PL have been adopted under Section 514 of the Act. However,

1. PhotoDerm[®] PL is an electro medical device and conforms with the voluntary international standard IEC601.1-1, Medical Electrical Equipment, Part 1: General Requirements for Safety.
2. Although PhotoDerm[®] PL is not a laser device, substantial equivalence for laser devices is being claimed. As such ESC has made efforts to comply, where applicable, with 21 CFR 1040.1 FDA laser performance standard.

In summary we believe that the analysis, the clinical data and the standards which the PhotoDerm[®] PL meets make it substantially equivalent to predicate devices.