U.S. Food and Drug Administration
510K Document Mail Center HFZ-401
Center for Medical Devices
390 Piccard Drive
Rockville, Maryland 20850

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To: Document Control Clerk

This summary of 510K safety and effectiveness for the BERGEN 610 Coagulator is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807,92.

A 0-50 digital display power setting indicator provides the operator a parallax free reading of the power setting (+/- 5watts, full scale @ 100 ohms).

A bar graph display output current monitor provides the operator a relative measure of the output current amplitude and to denote the presence of output energy during activation.

The handswitch is powered by an independent low voltage (7 Vdc) isolated power supply.

Audio and Visual monitors are in accord with IEC 601-1-2 and ANSI HF-18 guidelines.

RF and Low Frequency leakages are well within IEC 601-1-2 and ANSI HF-18 safety guide lines lines for isolated (body floating) bipolar coagulators.

his device is substantially equivalent to existing approved devices.

Sincerely,

Roger Oosten

Date 11/15/96

Roger Oosten
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