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To Whom It May Concern:

Megadyne Medical Products, the Electrosurgical Authority is the manufacturer of the MEGA 2000 and MEGA Soft Family of Reusable Patient Return Electrodes. The MEGA 2000 and MEGA Soft incorporate a current limiting technology which protects the patient from electrosurgical burns at the pad site. In fact these pads have been used in over **30 Million procedures without a pad site burn!**

In the instructions for use for the Mega 2000 and Mega Soft it states, ***“The Mega 2000 and Mega Soft utilize current limiting technology which has been determined to be safer than the contact quality monitoring system inherent in recent electrosurgical generator design and thus does not use CQM technology. ”***

This statement in the instructions for use and the supporting data was submitted for FDA review under 510K number K080741 which was subsequently cleared for market on 16 December 2008. MEGADYNE declares that the MEGA 2000 and MEGA Soft family of products are %Safer than CQM+. This could also mean %Safer than REM+, REM (Return Electrode Monitoring), is a registered trademark of Valleylab.

Not only are the Mega 2000 and Mega Soft easy to use and cost effective, but they are environmentally friendly and reduce the risk of pressure ulcers, and are Safer than REM. Protect your patients with the Mega 2000 and Mega Soft Reusable Patient Return Electrodes from MEGADYNE.

Sincerely,

Rob Farnsworth

Rob Farnsworth, President and CEO
Megadyne Medical Products