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LMI MEDICAL

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SUMMARY OF SAFETY AND EFFECTIVENESS

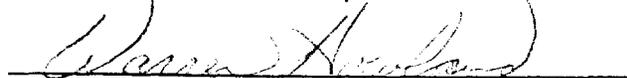
510(k) Premarket Notification
ElectroBlue® ECG Electrodes
LMI Medical
Division of Ludlow Technical Products
4275 Airwest Drive S. E.
Grand Rapids, MI 49512

LMI Medical considers their ElectroBlue® ECG Electrodes to be safe and effective for use with electrocardiograph monitors which are used for recording the electric activity of the myocardium to detect abnormal transmission of small electrical impulses through the conductive tissue surrounding the heart, when used according to the intended procedures as related in the instructions accompanying the product. The function of the LMI Medical ElectroBlue® Electrodes is to detect and transmit these small electrical impulses to the electrocardiograph monitors where they are processed and plotted.

The safety issues of these devices were evaluated to the ANSI/AAMI specification EC12-1991 whereby this standard "establishes minimum labeling, safety, and performance requirements for disposable electrodes used for diagnostic electrocardiograph (ECG) or ECG monitoring". The ANSI/AAMI standard EC12-1991 covers all facets of Disposable ECG electrodes. The LMI Medical ElectroBlue® disposable ECG electrodes were tested according to section: 3.2.2 "Electrical Performance", which covers AC impedance, DC offset Voltage, Combined offset instability and internal noise, Defibrillation overload recovery, Bias current tolerance; section 3.3.1 which covers Biological response; Section 4.2 which covers Performance, Packaging and shelf life, Tests for electrical performance; and section 4.3 Safety requirements, which covers Biological response evaluation, Cytotoxicity, Sensitization, Irritation, and Intracutaneous reactivity. LMI Medical's ElectroBlue® disposable ECG electrodes met these listed requirements of the ANSI/AAMI standard EC12-1991. These results are on file at LMI Medical.

The LMI Medical ElectroBlue® disposable ECG electrodes are substantially equivalent to products existing in the market place. NDM and Nikomed are two companies which offer products like LMI Medical ElectroBlue® disposable ECG electrodes. The LMI Medical electrode functions the same as the NDM and the Nikomed disposable ECG electrodes. The products are all the same in their construction using medical grade foam, polypropylene cloth, clear vinyl, medical grade adhesive, silver coated carbon loaded ABS snaps, and a conductive hydrogel with a polyurethane cover release liner.

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92


Warren Howland
Director of Development, Hydrogels

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