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Digital Conductance Meter - The Jayms Company

K924313

I. 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS DATA FOR THE
Digital Conductance Meter (Revised 7 November 1995)

Commercially available biofeedback devices measure the resistance of the skin and are used for relaxation training. These devices operate with a direct current to measure the resistance or an alternating current to measure impedance. Several biofeedback devices were marketed prior to 28 May 1976; and other substantially equivalent devices have been marketed since 1976, pursuant to the FDA's 510(k) process.

The Digital Conductance Meter (DCM) has the same technological features as other predicate Class II Biofeedback devices. Like the predicate devices, the DCM is functionally an ohmmeter. Like the predicate devices, the DCM is noninvasive and uses a low voltage to measure skin resistance. The DCM has the same electrical characteristics as predicate devices that are legally marketed as safe.

The intended use of the DCM is for relaxation training during the biofeedback process. The purpose of the skin conductance data is for the patient to receive visual and audio feedback and for the data to be recorded for reviewing and for monitoring. During operation of the predicate devices, the visual and audio feedback conveys information to the patient and the operator about the biofeedback response.

Like predicate devices, the DCM uses ohmmeter, audio and video hardware that conveys information about the skin conductance value during biofeedback. Predicate devices include the AT64 Skin Conductance Response (SCR) by Autogenic Systems Inc. (620 Wheat Lane, Wood Dale, IL, 60191) and the Biofeedback System/3 by Davicon (755 Middlesex, Billerica, MA). Those biofeedback devices were marketed prior to 1976. The DCM is also equivalent to the biofeedback functions of the Feedback Electrodermal Response Model EDR-100 (K770790) by Bio-Feedback Systems, Inc. (2736 47th Street, Boulder, CO, 80301).

In design, the Digital Conductance Meter, the AT64 SCR and the Davicon Biofeedback System/3 use a personal computer. The DCM and the System/3 use the computer to display, print and store conductance data. The System/3 and the DCM also allow a description of a protocol to be entered and saved for later recall. The AT64 SCR uses a personal computer to print data.

The materials of the DCM are equivalent to the materials used by other biofeedback. The materials form the ohmmeter circuit, display circuit and audio circuit. The DCM ohmmeter circuit can be selected for direct current (DC)

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output which is substantially equivalent to the AT64 SCR ohmmeter circuit or selected for alternating current (AC) output which is substantially equivalent to the EDR-100 and the System/3 ohmmeter circuits. The DCM has audio and video feedback signals which are substantially equivalent to the tones and the displays of the pre-1976 and predicate devices.

The use of the Digital Conductance Meter is equivalent to the use of the pre-1976 and predicate biofeedback devices. The biofeedback process is noninvasive and uses a low voltage to measure skin resistance. The pre-1976 and predicate biofeedback devices on the market have shown biofeedback to be safe and effective for relaxation training.