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Section 16: **510(k) SUMMARY OF SAFETY AND EFFECTIVENESS**
April 2, 1996

1. Establishment Information

Manufacturer/Submitter:	Marquette Electronics, Inc. 100 Marquette Drive Jupiter, FL 33469
Contact Name/Phone #	Michael Laughran Regulatory Affairs Marquette Electronics, Inc. Phone: (407) 574-5000

2. General Device Information

Common/Usual Name:	Electrocardiograph (ECG) Electrode
Trade/Proprietary Name:	BodyTrode
Classification Name:	Electrocardiograph electrode (CFR 870.2360)
Device Classification:	Class II
Performance Standards:	None established under section 514

3. Substantial Equivalence:

BodyTrode is substantially equivalent to Marquette ECG electrodes which are currently legally marketed under 510(k) 833695.

4. Device Description:

The Marquette BodyTrode ECG Electrodes are adhesive hydrogelled, single use ECG electrodes intended for use with adult and pediatric patients. The product is a polymer electrode comprised of three elements: a top polymer, a conductive adhesive hydrogel, and a radiotranslucent stud. The BodyTrode electrodes are applied to the patient's skin surface to acquire electrocardiographic activity of the heart. They are used in combination with patient leadwires, cables, and a monitor to display and/or analyze a patient's ECG.

5. Intended Use:

The BodyTrode is a short term, single use (disposable), adult and pediatric ECG electrode which is applied to the intact skin surface to acquire electrocardiographic activity of the heart which can be displayed and analyzed when used in combination with leadwires, cables, and a monitor. They are intended to be used in both hospital and prehospital settings under the direction of a licensed health care practitioner.

Section 16: **510(k) SUMMARY OF SAFETY AND EFFECTIVENESS** (continued)

6. Comparison to legally marketed predicate device.

CHARACTERISTIC	PREDICATE DEVICE PN 9408-401	PROPOSED DEVICE BODYTRODE
Intended Use	A disposable device for the detection of physiological potentials such as ECG, EEG, etc. through skin surface contact.	The BodyTrode is a short term, single use (disposable), adult and pediatric ECG electrode which is applied to the intact skin surface to acquire electrocardiographic activity of the heart which can be displayed and analyzed when used in combination with leadwires, cables, and a monitor. They are intended to be used in both hospital and prehospital settings under the direction of a licensed health care practitioner.
Materials/Construction	Oval lamination consisting of an adhesive coated foam pad and ring , a styrene ring, and conductive gel which is connected by a silver/silver chloride coated radiotranslucent plastic electrode and stud. The assembly is placed in a plastic holder and packaged in foil coated paper.	Round lamination consisting of a layer of conductive adhesive hydrogel and a top polymer with a silver/silver chloride coated radiotranslucent plastic stud. The assembly is placed in a plastic holder and packaged in foil coated paper.
Expiration Date	15 months from date of manufacture	12 months from date of manufacture

7. The following non-clinical tests were conducted and submitted for determination of substantial equivalence.

- Tests recommended in ANSI/AAMI voluntary standard of EC12-1991 with package aging using both real time and the Von't Hoff rule were conducted to demonstrate performance and technological characteristics.
- Bio-compatibility tests were conducted for the patient contact materials (the hydrogel). The tests were selected in accordance to ISO 10993-1:1992 and the FDA Matrix.

8. Conclusion

Testing done on the proposed BodyTrode and the predicate Marquette ECG electrode (PN 9408-401) indicates that the proposed provides an equivalent when compared to the ANSI/AAMI standard of EC12-1991 and ISO 10993-1:1992 and the FDA Matrix when tested as specified in the pre-market submission.

Marquette Electronics, Inc. concludes that the proposed BodyTrode is as safe and effective and performs substantially equivalent to the predicate Marquette ECG Electrode.