

K950943

**Summary of Safety and Effectiveness for
Ultra Ease Ultrasound Gel Pad**

I. General Information

Device Generic Name: Ultrasound Gel Pad
Device Trade Name: Ultra Ease Ultrasound Gel Pad

Applicant's Name and Address: LecTec Corporation
10701 Red Circle Drive
Minnetonka, MN 55343

510(k) Number: Unknown

Aquasonic Ultrasonic
Transmission Gel and
Aquaflex Ultrasound Gel Pad

Parker Laboratories
Orange, New Jersey 07050

Date of Judgement of Substantial

Equivalence: Unknown

II. Description of Conditions for Which the Device is Indicated

Ultra Ease Ultrasound Gel Pad is indicated for use as an ultrasound transmission gel to be used in conjunction with an Ultrasonic Blood Flow Detector to auscultate peripheral vascular perfusion.

III. Device Description

Ultra Ease Ultrasound Gel Pad is a non-irritating, rectangular shaped pad, that consists of a medical grade foam tape ring, a solid hydrogel transmission layer, and a polyester film cover. The pads are individually packaged in heat sealed paper/poly/foil/poly pouches.

IV. Alternatives

Other ultrasound transmission gels are alternatives for the Ultra Ease Ultrasound Gel Pad.

V. Potential Adverse Effects

Potential adverse effects associated with Ultra Ease Ultrasound Gel Pad are the same as those associated with other ultrasound transmission gels.

VI. Summary of Studies

Skin contact materials have passed a Primary Skin Irritation Test, a Repeated Insult Patch Tests (on 50 human subjects) and an Agarose Overlay Cytotoxicity Test to demonstrate pad safety. Clinical evaluation shows the pads are effective for the intended use.

VII. Conclusion

The information presented for the Ultra Ease Ultrasound Gel Pad demonstrates that it will perform in a safe and effective manner, as intended.