

Indications for Use

510(k) Number (if known): 101429

K101429

SEP 15 2010

Device Name: ECO Supergel

Indications for Use:

ECO SUPERGEL® is a transmission gel media used with ultrasonic pulsed echo imaging systems. The gel, when applied on the defined area of the body, facilitates the use of the system, which is intended to project a pulsed sound beam into body tissue to determine the depth or location of the tissue interfaces and to measure the duration of an acoustic pulse from the transmitter to the tissue interface and back to the receiver.

Prescription Use x
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF
NEEDED)

Concurrence of CDRH, ~~Office of Device Evaluation (ODE)~~ OIDVD

Division Sign-Off



(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

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