

K181363 EcoVue Sterile and Non-Sterile Ultrasound GelsJun 13, 2018
21 days to decisionK181363 · Product code: **MUI** · Radiology
Source: <https://www.510kdatabase.net/k181363/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Media, Coupling, Ultrasound (MUI)
Date received	May 23, 2018
Decision date	Jun 13, 2018
Days to decision	21 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	H R Pharmaceuticals, Inc.
Location	York, PA, US
Contact	Colby Wiesman
510(k) history	2 submissions · 2 cleared · 2018-2020

REGULATORY CONSULTANT

Consulting firm	Regulatory Technology Services, LLC
Contact	Mark Job

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

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