

K190591 Safergel Sterile Ultrasound GelOct 4, 2019
211 days to decisionK190591 · Product code: **MUI** · Radiology
Source: <https://www.510kdatabase.net/k190591/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Media, Coupling, Ultrasound (MUI)
Date received	Mar 7, 2019
Decision date	Oct 4, 2019
Days to decision	211 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	Safersonic Us, Inc.
Location	Highland Park, IL, US
Contact	David L. Seitelman
510(k) history	1 submissions · 1 cleared · 2019-2019

REGULATORY CONSULTANT

Consulting firm	Regulatory Insight, Inc.
Contact	Kevin Walls

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

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