FDA 510(k) Premarket Notification

K190591 Safergel Sterile Ultrasound Gel

CLEARED

Oct 4, 2019
211 days to decision

K190591 · 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