FDA 510(k) Premarket Notification

K163026 Ultra/Phonic Scanning Gel

CLEARED

Jan 9, 2018
435 days to decision

K163026 · Product code: **MUI** · Radiology
Source: https://www.510kdatabase.net/k163026/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Media, Coupling, Ultrasound (MUI)
Date received	Oct 31, 2016
Decision date	Jan 9, 2018
Days to decision	435 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Pharmaceutical Innovations, Inc.**
Location	Newark, NJ, US
Contact	Shirley J. Bergman
510(k) history	5 submissions · 5 cleared · 1996-2018