FDA 510(k) Premarket Notification

K182880 Halifax Imaging Kit

CLEARED

Oct 31, 2018
16 days to decision

K182880 · Product code: **KPR** · Radiology
Source: https://www.510kdatabase.net/k182880/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, X-ray, Stationary (KPR)
Date received	Oct 15, 2018
Decision date	Oct 31, 2018
Days to decision	16 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Halifax Biomedical, Inc.**
Location	Dundas, CA
Contact	Crystal Jones
510(k) history	5 submissions · 5 cleared · 2009-2018

REGULATORY CONSULTANT

Consulting firm	**Kamm & Associates**
Contact	Daniel Kamm

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