FDA 510(k) Premarket Notification

K163192 Comfort EC710

CLEARED

Apr 10, 2017
146 days to decision

K163192 · Product code: **LNH** · Radiology
Source: https://www.510kdatabase.net/k163192/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Nuclear Magnetic Resonance Imaging (LNH)
Date received	Nov 15, 2016
Decision date	Apr 10, 2017
Days to decision	146 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Alltech Medical Systems America, Inc.**
Location	Solon, OH, US
Contact	MICHAELEEN DOM
510(k) history	4 submissions · 4 cleared · 2008-2017