FDA 510(k) Premarket Notification

K161682 GE Lunar DXA Bone Densitometers with enCORE version 17

CLEARED

Dec 2, 2016
168 days to decision

K161682 · Product code: **KGI** · Radiology
Source: https://www.510kdatabase.net/k161682/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Densitometer, Bone (KGI)
Date received	Jun 17, 2016
Decision date	Dec 2, 2016
Days to decision	168 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**GE Medical Systems Ultrasound & Primary Care Diagnostics, LLC**
Location	Wauwatosa, WI, US
Contact	Nicole Landreville
510(k) history	14 submissions · 14 cleared · 2016-2026