FDA 510(k) Premarket Notification

K173408 Mammomat Revelation

CLEARED

Mar 21, 2018
140 days to decision

K173408 · Product code: **MUE** · Radiology
Source: https://www.510kdatabase.net/k173408/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Full Field Digital, System, X-ray, Mammographic (MUE)
Date received	Nov 1, 2017
Decision date	Mar 21, 2018
Days to decision	140 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Siemens Medi Cal Solutions, Inc.**
Location	Ann Arbor, MI, US
Contact	Denise Adams
510(k) history	32 submissions · 32 cleared · 2004-2020