FDA 510(k) Premarket Notification

K173041 3DIEMME RealGUIDE

CLEARED

Dec 20, 2018
448 days to decision

K173041 · Product code: **LLZ** · Radiology
Source: https://www.510kdatabase.net/k173041/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Sep 28, 2017
Decision date	Dec 20, 2018
Days to decision	448 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**3Diemme , Ltd.**
Location	Cantu, IT
Contact	Alessandro Montroni
510(k) history	1 submissions · 1 cleared · 2018-2018

REGULATORY CONSULTANT

Consulting firm	**Registar Corp**
Contact	Lara Luzak

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