FDA 510(k) Premarket Notification

K213081 CLISIS SYSTEMS, Discovery RF180

CLEARED

Oct 26, 2021
33 days to decision

K213081 · Product code: **IZF** · Radiology
Source: https://www.510kdatabase.net/k213081/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Tomographic (IZF)
Date received	Sep 23, 2021
Decision date	Oct 26, 2021
Days to decision	33 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	**General Medical Merate S.P.A**
Location	Seriate, Bergamo, IT
Contact	Luca Bianchessi
510(k) history	7 submissions · 7 cleared · 1982-2021

REGULATORY CONSULTANT

Consulting firm	**THEMA S.r.l.**
Contact	Marisa Testa

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