FDA 510(k) Premarket Notification

K203509 SMART FINDER

CLEARED

Jul 14, 2021
226 days to decision

K203509 · Product code: **IZH** · Radiology
Source: https://www.510kdatabase.net/k203509/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, X-ray, Mammographic (IZH)
Date received	Nov 30, 2020
Decision date	Jul 14, 2021
Days to decision	226 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	**Ims Giotto S.P.A.**
Location	Sasso Marconi, IT
Contact	Antonella Rossi
510(k) history	2 submissions · 2 cleared · 2020-2021

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

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Device record: https://www.510kdatabase.net/k203509/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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