

K211679 Xtractor deviceFeb 17, 2022
261 days to decisionK211679 · Product code: **DRE** · Cardiovascular
Source: <https://www.510kdatabase.net/k211679/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dilator, Vessel, For Percutaneous Catheterization (DRE)
Date received	Jun 1, 2021
Decision date	Feb 17, 2022
Days to decision	261 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Xcardia Innovation , Ltd.
Location	Rehovot, IL
Contact	Benny Rousso
510(k) history	1 submissions · 1 cleared · 2022-2022

REGULATORY CONSULTANT

Consulting firm	Orly Maor
Contact	Orly Maor

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k211679/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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