FDA 510(k) Premarket Notification

CLEARED

K211001 C-Qual M™ Breastboard

May 20, 2021
48 days to decision

K211001 · Product code: **IYE** · Radiology
Source: https://www.510kdatabase.net/k211001/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Accelerator, Linear, Medical (IYE)
Date received	Apr 2, 2021
Decision date	May 20, 2021
Days to decision	48 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Monarch™ Overhead Arm Positioner

APPLICANT

Company	**Medtec, Inc. Dba Civco Medical Solutions and Civco**
Location	Orange City, IA, US
Contact	Alena Newgren
510(k) history	1 submissions · 1 cleared · 2021-2021

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k211001/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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