FDA 510(k) Premarket Notification

K180395 EZ-IO Intraosseous Vascular Access System

CLEARED

Nov 9, 2018
269 days to decision

K180395 · Product code: **FMI** · General Hospital
Source: https://www.510kdatabase.net/k180395/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Needle, Hypodermic, Single Lumen (FMI)
Date received	Feb 13, 2018
Decision date	Nov 9, 2018
Days to decision	269 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Arrow International, Inc. (Subsidiary of Teleflex, Inc.)**
Location	Reading, PA, US
Contact	Frank Pelc
510(k) history	8 submissions · 7 cleared · 2015-2018

CLINICAL EVIDENCE - NCT01866475

Continuous Intraosseous Vascular Access Over 48 Hours

Status	Completed
Enrollment	127 patients (actual)
Study sites	1 site
Condition studied	Intraosseous Vascular Access
Primary purpose	Other
Study type	Interventional
Study design	Parallel
Masking	Open label
Completion date	Jul 1, 2016
Sponsor	Vidacare Corporation (Industry)

Primary outcome

Serious Complications From Intraosseous (IO) Access

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT01866475