FDA 510(k) Premarket Notification

K191488 SAM IO Intraosseous Access System

CLEARED

Nov 21, 2019
170 days to decision

K191488 · Product code: **FMI** · General Hospital
Source: https://www.510kdatabase.net/k191488/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Needle, Hypodermic, Single Lumen (FMI)
Date received	Jun 4, 2019
Decision date	Nov 21, 2019
Days to decision	170 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Sam? Medical Products, Inc.**
Location	Wilsonville, OR, US
Contact	Jeff Lipps
Website	http://www.sammedical.com/
510(k) history	1 submissions · 1 cleared · 2019-2019

Sam? Medical Products, Inc. is an emergency medical solutions manufacturer based in Wilsonville, Oregon. The company develops and distributes a broad range of trauma and emergency care devices for military, law enforcement, EMS, first responders, and hospital settings. The company has received FDA 510(k) clearance from total submission. Its cleared device portfolio focuses on General Hospital applications, with the SAM IO Intraosseous Access System cleared in 2019. This represents the company's regulatory activity on record. Company status: inactive. No FDA 510(k) clearan...

REGULATORY CONSULTANT

Consulting firm	**leanRAQA, LLC**
Contact	Michelle Lott

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