FDA 510(k) Premarket Notification

CLEARED

K222182 Radial Artery Compression Tourniquets

Jan 4, 2023
166 days to decision

K222182 · Product code: **DXC** · Cardiovascular
Source: https://www.510kdatabase.net/k222182/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Clamp, Vascular (DXC)
Date received	Jul 22, 2022
Decision date	Jan 4, 2023
Days to decision	166 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	**Beijing Demax Medical Technology Co.,Ltd**
Location	Guangzhou, CN
Contact	Anny Zhang
510(k) history	4 submissions · 4 cleared · 2015-2024

REGULATORY CONSULTANT

Consulting firm	**Guangzhou Osmunda Medical Device Consulting Co., Ltd.**
Contact	Olivia Meng

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