FDA 510(k) Premarket Notification

CLEARED

K182289 Sterile High-pressure Angiographic Syringes for Single-use

Oct 10, 2018
48 days to decision

K182289 · Product code: **DXT** · Cardiovascular
Source: https://www.510kdatabase.net/k182289/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Injector And Syringe, Angiographic (DXT)
Date received	Aug 23, 2018
Decision date	Oct 10, 2018
Days to decision	48 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Shenzhen Baoan Medical Supplies Co., Ltd.**
Location	Shenzhen, CN
Contact	Mingan Mu
510(k) history	2 submissions · 2 cleared · 2016-2018

REGULATORY CONSULTANT

Consulting firm	**Mid-Link Consulting Co, Ltd.**
Contact	Diana Hong

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