

K182289 Sterile High-pressure Angiographic Syringes for Single-useOct 10, 2018
48 days to decisionK182289 · 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](https://accessdata.fda.gov)

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k182289/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 19, 2026