

K201395 Sterile High-pressure Angiographic Syringes for single-useOct 28, 2020
154 days to decisionK201395 · Product code: DXT · General Hospital
Source: <https://www.510kdatabase.net/k201395/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Injector And Syringe, Angiographic (DXT)
Date received	May 27, 2020
Decision date	Oct 28, 2020
Days to decision	154 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Youwo (Guangzhou) Medical Device Co., Ltd.
Location	Guangzhou, CN
Contact	Meijin Song
510(k) history	1 submissions · 1 cleared · 2020-2020

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/k201395/> 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 28, 2026