

K200463 Huber Needle Infusion Set, Safety Huber Needle Infusion SetApr 7, 2021
407 days to decisionK200463 · Product code: PTI · General Hospital
Source: <https://www.510kdatabase.net/k200463/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Non-coring (huber) Needle (PTI)
Date received	Feb 25, 2020
Decision date	Apr 7, 2021
Days to decision	407 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Jiangsu Caina Medical Co.,Ltd
Location	Jiangyin, CN
Contact	Jianwei Pan
510(k) history	21 submissions · 21 cleared · 2018-2024

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/k200463/> 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 May 14, 2026