

K222980 Pentax Medical Valve SetNov 21, 2022
54 days to decisionK222980 · Product code: **ODC** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k222980/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Endoscope Channel Accessory (ODC)
Date received	Sep 28, 2022
Decision date	Nov 21, 2022
Days to decision	54 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Yangzhou Fartley Medical Instrument Technology Co., Ltd.
Location	Yangzhou, CN
Contact	Tina Han
510(k) history	7 submissions · 7 cleared · 2022-2025

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