

K212430 BONREE Nelaton CatheterApr 29, 2022
268 days to decisionK212430 · Product code: **EZD** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k212430/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Straight (EZD)
Date received	Aug 4, 2021
Decision date	Apr 29, 2022
Days to decision	268 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Bonree Medical Co., Ltd.
Location	Zhongshan, CN
Contact	He Hongbo
510(k) history	1 submissions · 1 cleared · 2022-2022

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