

K170233 Disposable Urinary Catheter (PVC Urinary Catheter, Silicone Urinary Catheter, Latex Urinary Catheter)Oct 13, 2017
261 days to decisionK170233 · Product code: **EZD** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k170233/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Straight (EZD)
Date received	Jan 25, 2017
Decision date	Oct 13, 2017
Days to decision	261 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Zhanjiang Star Enterprise Co., Ltd.
Location	Zhanjiang, CN
Contact	Rongsheng Tang
510(k) history	2 submissions · 2 cleared · 2017-2018

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k170233/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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