

K192468 Male, Nelaton-tip Ready-to-Use Hydrophilic CatheterNov 27, 2019
79 days to decisionK192468 · Product code: **GBM** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k192468/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Urethral (GBM)
Date received	Sep 9, 2019
Decision date	Nov 27, 2019
Days to decision	79 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Femal, Nelaton-tip Ready-to-Use Hydrophilic Catheter; Pediatric, Nelaton-tip Ready-to-Use Hydrophilic Catheter Intermittent Catheter; Male, Tapered-Tip Tiemann Ready-to-Use Hydrophilic Catheter; Male, Olive-Tip Tiemann Ready-to-Use Hydrophilic Catheter

APPLICANT

Company	Hangzhou Bever Medical Devices Co., Ltd.
Location	Hangzhou, Zhejiang, CN
Contact	Allyson Zhou
510(k) history	4 submissions · 4 cleared · 2012-2019

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