

K102833 DISPOSABLE HEMODIALYSIS ACCESS CATHETER SETSNov 18, 2011
415 days to decisionK102833 · Product code: **MPB** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k102833/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Hemodialysis, Non-implanted (MPB)
Date received	Sep 29, 2010
Decision date	Nov 18, 2011
Days to decision	415 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Foshan Nanhai Bai HE Medical Technology Co., Ltd.
Location	Shanghai, CN
Contact	Diana Hong
510(k) history	2 submissions · 2 cleared · 2007-2011

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k102833/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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