

K260134 Baby Nasal Aspirator (BN006, BN006-A, BN006-B, BN006-C, BN006-D, BN02May 15, 2026
119 days to decisionK260134 · Product code: BTA · Ear, Nose, Throat
Source: <https://www.510kdatabase.net/k260134/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Pump, Portable, Aspiration (manual Or Powered) (BTA)
Date received	Jan 16, 2026
Decision date	May 15, 2026
Days to decision	119 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	BN008, BN008-A, BN008-B, BN008-C, BN008-D, BC-021)

APPLICANT

Company	Shenzhen Root Innovation Technology Co., Ltd.
Location	Shenzhen, CN
Contact	Haiyan Wen
510(k) history	11 submissions · 11 cleared · 2024-2026

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k260134/>. Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 6, 2026