

K230258 BB 8 Sinus Dilation KitMay 25, 2023
114 days to decisionK230258 · Product code: LRC · Ear, Nose, Throat
Source: <https://www.510kdatabase.net/k230258/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Instrument, Ent Manual Surgical (LRC)
Date received	Jan 31, 2023
Decision date	May 25, 2023
Days to decision	114 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Excelent, Inc.
Location	Durham, NC, US
Contact	Kashif Mazhar
510(k) history	1 submissions · 1 cleared · 2023-2023

REGULATORY CONSULTANT

Consulting firm	Brosseau Consulting, LLC
Contact	Bryan Brosseau

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

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