

K171851 SOFTXILMar 16, 2018
268 days to decisionK171851 · Product code: **MIB** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k171851/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Elastomer, Silicone Block (MIB)
Date received	Jun 21, 2017
Decision date	Mar 16, 2018
Days to decision	268 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Bistool
Location	Seoul, KR
Contact	Eunhyun Bae
510(k) history	1 submissions · 1 cleared · 2018-2018

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k171851/> 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 May 30, 2026