

K200057 bioli IOL Delivery SystemJun 4, 2020
143 days to decisionK200057 · Product code: **MSS** · Ophthalmic
Source: <https://www.510kdatabase.net/k200057/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Folders And Injectors, Intraocular Lens (iol) (MSS)
Date received	Jan 13, 2020
Decision date	Jun 4, 2020
Days to decision	143 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Ast Products, Inc.
Location	Billerica, MA, US
Contact	William Lee
510(k) history	4 submissions · 4 cleared · 2015-2020

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k200057/> 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 28, 2026