

K211273 Harmonic Hand Piece, Blue, Harmonic Hand Piece, GrayMay 21, 2021
24 days to decisionK211273 · Product code: **LFL** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k211273/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Instrument, Ultrasonic Surgical (LFL)
Date received	Apr 27, 2021
Decision date	May 21, 2021
Days to decision	24 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Ethicon Endo-Surgery, LLC
Location	Blue Ash, OH, US
Contact	Nathan Anderson
Website	https://www.jnjmedtech.com
510(k) history	69 submissions · 69 cleared · 2006-2026

REGULATORY CONSULTANT

Consulting firm	Ethicon Endo-Surgery, Inc.
Contact	Ruth James

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k211273/> 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 13, 2026