

K133554 SURGICAL LIGHT HANDLE COVERApr 8, 2014
140 days to decisionK133554 · Product code: **FTA** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k133554/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Light, Surgical, Accessories (FTA)
Date received	Nov 19, 2013
Decision date	Apr 8, 2014
Days to decision	140 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Microtek Medical, Inc. an Ecolab Company
Location	Saint Paul, MN, US
Contact	ANDY ROLLER
510(k) history	1 submissions · 1 cleared · 2014-2014

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k133554/> 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 7, 2026