

K143738 DSS Sinusplasty Balloon CatheterAug 27, 2015
240 days to decisionK143738 · Product code: **LRC** · Ear, Nose, ThroatSource: <https://www.510kdatabase.net/k143738/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Instrument, Ent Manual Surgical (LRC)
Date received	Dec 30, 2014
Decision date	Aug 27, 2015
Days to decision	240 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Intuit Medical Products, LLC
Location	Sugar Hill, GA, US
Contact	Jack Griffis
510(k) history	3 submissions · 3 cleared · 2015-2020

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k143738/> 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 18, 2026