FDA 510(k) Premarket Notification

K143738 DSS Sinusplasty Balloon Catheter

CLEARED

Aug 27, 2015
240 days to decision

K143738 · Product code: **LRC** · Ear, Nose, Throat
Source: 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