

K201398 SINUSPRIME Dilation SystemOct 15, 2020
140 days to decisionK201398 · Product code: **LRC** · Ear, Nose, Throat
Source: <https://www.510kdatabase.net/k201398/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Instrument, Ent Manual Surgical (LRC)
Date received	May 28, 2020
Decision date	Oct 15, 2020
Days to decision	140 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Stryker Ent
Location	Plymouth, MN, US
Contact	Bruce Backlund
510(k) history	3 submissions · 3 cleared · 2020-2020

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