

K131177 SINUFLUSH LAVAGE SYSTEMSep 20, 2013
148 days to decisionK131177 · Product code: **KAR** · Ear, Nose, ThroatSource: <https://www.510kdatabase.net/k131177/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Irrigator, Sinus (KAR)
Date received	Apr 25, 2013
Decision date	Sep 20, 2013
Days to decision	148 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Hedgepath, LLC
Location	Tampa, FL, US
Contact	FRANK E O'CONNOR; DONNELL, JR MD.
510(k) history	1 submissions · 1 cleared · 2013-2013

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