

K201877 OtoSet- Ear Cleaning SystemNov 5, 2020
121 days to decisionK201877 · Product code: **KYZ** · Ear, Nose, Throat
Source: <https://www.510kdatabase.net/k201877/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Syringe, Irrigating (non Dental) (KYZ)
Date received	Jul 7, 2020
Decision date	Nov 5, 2020
Days to decision	121 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Safkan, Inc.
Location	Tucson, AZ, US
Contact	Sahil Diwan
510(k) history	1 submissions · 1 cleared · 2020-2020

REGULATORY CONSULTANT

Consulting firm	Acknowledge Regulatory Strategies, LLC
Contact	Allison Komiyama

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

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