FDA 510(k) Premarket Notification

K201472 VenSure Balloon Device, VenSure Nav Balloon Device

CLEARED

Aug 26, 2020
84 days to decision

K201472 · Product code: **LRC** · Ear, Nose, Throat
Source: https://www.510kdatabase.net/k201472/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Instrument, Ent Manual Surgical (LRC)
Date received	Jun 3, 2020
Decision date	Aug 26, 2020
Days to decision	84 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Fiagon GmbH**
Location	Hennigsdorf, DE
Contact	Dirk Mucha
510(k) history	15 submissions · 15 cleared · 2014-2023