

K163400 Orbit InserterJul 26, 2017
233 days to decisionK163400 · Product code: **KZH** · General Hospital
Source: <https://www.510kdatabase.net/k163400/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Introducer, Syringe Needle (KZH)
Date received	Dec 5, 2016
Decision date	Jul 26, 2017
Days to decision	233 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Ypsomed AG
Location	Burgdorf, CH
Contact	STEPHAN AFFOLTER
510(k) history	12 submissions · 12 cleared · 2010-2025

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