FDA 510(k) Premarket Notification

K203800 SyntrFuge System

CLEARED

Jul 2, 2021
186 days to decision

K203800 · Product code: **MUU** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k203800/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Suction, Lipoplasty (MUU)
Date received	Dec 28, 2020
Decision date	Jul 2, 2021
Days to decision	186 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Syntr Health Technologies, Inc.**
Location	Irvine, CA, US
Contact	Ahmed Zobi
510(k) history	1 submissions · 1 cleared · 2021-2021

REGULATORY CONSULTANT

Consulting firm	**Bqc Consulting, LLC**
Contact	Nevine Erian

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