FDA 510(k) Premarket Notification

K193539 REVOLVE ENVI 600 Advanced Adipose System

CLEARED

May 28, 2020
160 days to decision

K193539 · Product code: **MUU** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k193539/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Suction, Lipoplasty (MUU)
Date received	Dec 20, 2019
Decision date	May 28, 2020
Days to decision	160 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Lifecell Corporation**
Location	Branchburg, NJ, US
Contact	Bozhana Hegarty
510(k) history	5 submissions · 5 cleared · 2014-2020