FDA 510(k) Premarket Notification

K190278 AuraGen 123 Suction Lipoplasty System (A123)

CLEARED

May 3, 2019
84 days to decision

K190278 · Product code: **MUU** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k190278/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Suction, Lipoplasty (MUU)
Date received	Feb 8, 2019
Decision date	May 3, 2019
Days to decision	84 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Auragen Aesthetics, LLC**
Location	Weston, MA, US
Contact	Yiannis Monovoukas
510(k) history	1 submissions · 1 cleared · 2019-2019

REGULATORY CONSULTANT

Consulting firm	**Hogan Lovells US LLP**
Contact	Randy J. Prebula

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

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