

K242894 SanAgile™ Ultrasonic Surgery Advanced Portable Controller (SA10)Jun 18, 2025
268 days to decisionK242894 · Product code: LFL · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k242894/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Instrument, Ultrasonic Surgical (LFL)
Date received	Sep 23, 2024
Decision date	Jun 18, 2025
Days to decision	268 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	SanAgile™ Ultrasonic Surgery Advanced Dissector (SASD14); SanAgile™ Ultrasonic Surgery Advanced Dissector (SASD23); SanAgile™ Ultrasonic Surgery Advanced Dissector (SASD36); SanAgile™ Ultrasonic Surgery Advanced Dissector (SASD45)

APPLICANT

Company	Shanghai Saints Sages Surgical Co., Ltd.
Location	Shanghai, CN
Contact	Xue Ting
510(k) history	1 submissions · 1 cleared · 2025-2025

REGULATORY CONSULTANT

Consulting firm	Emergo Global Consulting, LLC
Contact	Giselle Zhang

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