

K201744 Su2ura Approximation DeviceJun 17, 2021
357 days to decisionK201744 · Product code: **OCW** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k201744/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Endoscopic Tissue Approximation Device (OCW)
Date received	Jun 25, 2020
Decision date	Jun 17, 2021
Days to decision	357 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Anchora Medical, Ltd.
Location	I.Z. Yokneam, IL
Contact	Yoni Epstein
510(k) history	1 submissions · 1 cleared · 2021-2021

REGULATORY CONSULTANT

Consulting firm	Duet-Medical Consulting, Ltd.
Contact	Eilat Ezra

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

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