

K192138 Rejuvapen NXTApr 9, 2020
245 days to decisionK192138 · Product code: **QAI** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k192138/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Microneedle Device (QAI)
Date received	Aug 8, 2019
Decision date	Apr 9, 2020
Days to decision	245 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Refine USA, LLC
Location	Jacksonville Beach, FL, US
Contact	Brian Smith
510(k) history	2 submissions · 2 cleared · 2012-2020

REGULATORY CONSULTANT

Consulting firm	Technireg, Inc.
Contact	Wayne Glover

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k192138/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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