FDA 510(k) Premarket Notification

K200044 SkinStylus SteriLock MicroSystem

CLEARED

Apr 10, 2020
93 days to decision

K200044 · Product code: **QAI** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k200044/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Microneedle Device (QAI)
Date received	Jan 8, 2020
Decision date	Apr 10, 2020
Days to decision	93 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Esthetic Education, LLC**
Location	Scottsdale, AZ, US
Contact	Marc C. Sanchez
510(k) history	1 submissions · 1 cleared · 2020-2020

REGULATORY CONSULTANT

Consulting firm	**Contract In-House Counsel and Consultants, LLC**
Contact	Marc C. Sanchez

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

CLINICAL EVIDENCE - NCT03366194

The Clinical Efficacy And Safety Of SkinStylus Microneedling System

Status	Completed
Enrollment	36 patients (actual)
Study sites	1 site
Condition studied	Cicatrix, Hypertrophic
Primary purpose	Treatment
Study type	Interventional
Study design	Single group
Masking	Open label
Completion date	Dec 1, 2018
Sponsor	Esthetic Education LLC (Industry)

Primary outcome

Number of Participants With Improvement Assessed Using the VAS Scar Scoring System

Secondary outcome

Number of Patients Self-Reporting Improvement Using the Validated Self-Assessed Scar Improvement Scale Satisfaction Survey

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT03366194