FDA 510(k) Premarket Notification

K220506 SkinPen Precision System

CLEARED

Mar 7, 2022
13 days to decision

K220506 · Product code: **QAI** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k220506/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Powered Microneedle Device (QAI)
Date received	Feb 22, 2022
Decision date	Mar 7, 2022
Days to decision	13 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Crown Aesthetics**
Location	Dallas, TX, US
Contact	Marie Fogartie
510(k) history	3 submissions · 3 cleared · 2021-2024