FDA 510(k) Premarket Notification

K180778 Exceed Microneedling Device

CLEARED

Sep 7, 2018
165 days to decision

K180778 · Product code: **QAI** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k180778/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Microneedle Device (QAI)
Date received	Mar 26, 2018
Decision date	Sep 7, 2018
Days to decision	165 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Mt. Derm GmbH**
Location	Berlin, DE
Contact	Anderas Pachten
510(k) history	3 submissions · 3 cleared · 2018-2024