FDA 510(k) Premarket Notification

K203826 LaserCap Family of Lasers 300, 224, 120 & 80

CLEARED

Mar 29, 2021
90 days to decision

K203826 · Product code: **OAP** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k203826/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Laser, Comb, Hair (OAP)
Date received	Dec 29, 2020
Decision date	Mar 29, 2021
Days to decision	90 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Transdermal Cap, Inc.**
Location	Cleveland, OH, US
Contact	Michael Rabin
510(k) history	3 submissions · 3 cleared · 2015-2021

REGULATORY CONSULTANT

Consulting firm	**Nst Consultants, Inc.**
Contact	Raymond R Blanche

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