

K191166 DigniCap DeltaJun 26, 2019
56 days to decisionK191166 · Product code: **PMC** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k191166/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Scalp Cooling System (PMC)
Date received	May 1, 2019
Decision date	Jun 26, 2019
Days to decision	56 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Dignitana, Inc.
Location	Dallas, TX, US
Contact	William Cronin
510(k) history	1 submissions · 1 cleared · 2019-2019

REGULATORY CONSULTANT

Consulting firm	Experien Group
Contact	Valerie Defiesta-Ng

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/k191166/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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