

**K170871 DigniCap Scalp Cooling System**Jul 3, 2017  
102 days to decisionK170871 · Product code: **PMC** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k170871/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Scalp Cooling System (PMC)
Date received	Mar 23, 2017
Decision date	Jul 3, 2017
Days to decision	102 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Dignitana AB</b>
Location	Lund, SE
Contact	Johan Ericsson
510(k) history	2 submissions · 1 cleared · 2015-2017

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k170871/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 14, 2026