

K192829 Demetra BDEM-01 DermatoscopeDec 13, 2019
72 days to decisionK192829 · Product code: **PSN** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k192829/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Light Based Imaging (PSN) |
| Date received | Oct 2, 2019 |
| Decision date | Dec 13, 2019 |
| Days to decision | 72 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Barco N.V. |
| Location | La Jolla, CA, US |
| Contact | Julie Vandecandelaere |
| Website | http://www.barco.com |
| 510(k) history | 60 submissions · 60 cleared · 1998-2024 |

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