

K240610 deepLiveJul 9, 2024
126 days to decisionK240610 · Product code: **NQQ** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k240610/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | System, Imaging, Optical Coherence Tomography (oct) (NQQ) |
| Date received | Mar 5, 2024 |
| Decision date | Jul 9, 2024 |
| Days to decision | 126 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Damae Medical |
| Location | Paris, FR |
| Contact | David Siret |
| Website | https://www.damae-medical.com |
| 510(k) history | 2 submissions · 2 cleared · 2024-2025 |

Damae Medical develops advanced imaging systems for skin analysis and clinical diagnostics. Based in Paris, France, the company specializes in non-invasive medical devices for dermatology and General & Plastic Surgery applications. The company's flagship technology, deepLive™, integrates LC-OCT (Line-field Confocal Optical Coherence Tomography) for 3D skin imaging with cellular resolution. Damae Medical has received FDA 510(k) clearances from total submissions, with all submissions focused on General & Plastic Surgery devices. The company achieved its first FDA clearance ...
