

K110375 BLUESHINE'S GOLD SERIESFeb 23, 2012
379 days to decisionK110375 · Product code: **PDZ** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k110375/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Lasers For Temporary Increase Of Clear Nail In Patients With Onychomycosis (PDZ) |
| Date received | Feb 9, 2011 |
| Decision date | Feb 23, 2012 |
| Days to decision | 379 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Blueshine Srl |
| Location | Mestre, Venice, IT |
| Contact | CHIARA RICCI |
| 510(k) history | 3 submissions · 3 cleared · 2006-2012 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k110375/> Data sourced from FDA 510(k) public records (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. - Generated June 15, 2026