

K193161 Pristine ScopeApr 21, 2020
158 days to decisionK193161 · Product code: **GCJ** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k193161/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Laparoscope, General & Plastic Surgery (GCJ) |
| Date received | Nov 15, 2019 |
| Decision date | Apr 21, 2020 |
| Days to decision | 158 days |
| Third-party review | No |
| Summary / Statement | Statement |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Pristine Surgical |
| Location | Manchester, NH, US |
| Contact | Stewart B. Davis |
| 510(k) history | 3 submissions · 3 cleared · 2019-2022 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k193161/> 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 May 26, 2026