

K160338 Triton SystemAug 5, 2016
179 days to decisionK160338 · Product code: **PBZ** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k160338/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Image Processing Device For Estimation Of External Blood Loss (PBZ) |
| Date received | Feb 8, 2016 |
| Decision date | Aug 5, 2016 |
| Days to decision | 179 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Gauss Surgical, Inc., |
| Location | Cupertino, CA, US |
| Contact | ARTIE KAUSHIK |
| 510(k) history | 6 submissions · 5 cleared · 2012-2017 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k160338/> 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 14, 2026