

**K250213 OptaBlate BVN Intraosseous Nerve Ablation System
(10mm Probe Single Kit)**

May 15, 2025
111 days to decision

K250213 · Product code: **GXI** · Neurology
Source: <https://www.510kdatabase.net/k250213/>

SUBMISSION DETAILS

| | |
|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Probe, Radiofrequency Lesion (GXI) |
| Date received | Jan 24, 2025 |
| Decision date | May 15, 2025 |
| Days to decision | 111 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |
| Other names | OptaBlate BVN Intraosseous Nerve Ablation System (10mm Probe Dual Kit) |

APPLICANT

| | |
|----------------|---|
| Company | Stryker Instruments |
| Location | Kalamazoo, MI, US |
| Contact | Dayana Manganese |
| 510(k) history | 72 submissions · 72 cleared · 1994-2026 |

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k250213/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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