

**K132908 TRUPOINT ARCH, NASION CUSHION, BITE CUP,
TRUPOINT ARCH STORAGE PLATE, TRUPOINT ARCH BASE
LOCK REPLACEMENT KIT**Mar 4, 2014
168 days to decisionK132908 · Product code: **IYE** · Radiology
Source: <https://www.510kdatabase.net/k132908/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Accelerator, Linear, Medical (IYE) |
| Date received | Sep 17, 2013 |
| Decision date | Mar 4, 2014 |
| Days to decision | 168 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Medtec, Inc. |
| Location | Orange City, IA, US |
| Contact | AMANDA STAHL |
| 510(k) history | 41 submissions · 41 cleared · 1993-2014 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k132908/>; 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 16, 2026