

K142198 BNX Fine Needle Aspiration SystemOct 8, 2014
58 days to decisionK142198 · Product code: **NEU** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k142198/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Marker, Radiographic, Implantable (NEU) |
| Date received | Aug 11, 2014 |
| Decision date | Oct 8, 2014 |
| Days to decision | 58 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Covidien, LLC |
| Location | Mansfield, MA, US |
| Contact | Saket Bhatt |
| 510(k) history | 88 submissions · 85 cleared · 2010-2026 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k142198/> 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 6, 2026