

K102226 DUAL INCU IJan 4, 2011
148 days to decisionK102226 · Product code: **FMZ** · General Hospital
Source: <https://www.510kdatabase.net/k102226/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Incubator, Neonatal (FMZ) |
| Date received | Aug 9, 2010 |
| Decision date | Jan 4, 2011 |
| Days to decision | 148 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Atom Medical Corporation |
| Location | Bunkyo-Ku, Tokyo, JP |
| Contact | TSUYOSHI SUGINO |
| 510(k) history | 10 submissions · 10 cleared · 2010-2013 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k102226/> 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 24, 2026