

K241007 Upper Arm Electronic Blood Pressure Monitor (U86E and TelliBP01)Oct 24, 2024
195 days to decisionK241007 · Product code: **DXN** · Cardiovascular
Source: <https://www.510kdatabase.net/k241007/>**SUBMISSION DETAILS**

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|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | System, Measurement, Blood-pressure, Non-invasive (DXN) |
| Date received | Apr 12, 2024 |
| Decision date | Oct 24, 2024 |
| Days to decision | 195 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

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|----------------|--|
| Company | Shenzhen Urion Technology Co., Ltd. |
| Location | Shenzhen, CN |
| Contact | Zhu Changming |
| 510(k) history | 7 submissions · 7 cleared · 2015-2026 |

REGULATORY CONSULTANT

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|-----------------|---|
| Consulting firm | Shenzhen Reanny Medical Devices Management Consulting Co.,Lt |
| Contact | Wang Reanny |

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k241007/>; 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 13, 2026