

**K190134 Full Automatic (NIBP) Blood Pressure Monitor-
HL158TB**

May 20, 2019
112 days to decision

K190134 · Product code: **DXN** · Cardiovascular
Source: <https://www.510kdatabase.net/k190134/>

SUBMISSION DETAILS

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Special |
| Device classification | System, Measurement, Blood-pressure, Non-invasive (DXN) |
| Date received | Jan 28, 2019 |
| Decision date | May 20, 2019 |
| Days to decision | 112 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Health & Life Co., Ltd. |
| Location | Taipei Hsien, TW |
| Contact | JS Hsu |
| 510(k) history | 60 submissions · 60 cleared · 1999-2021 |

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k190134/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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