

**K202757 CONTEC08A Electronic Sphygmomanometer,
CONTEC08C Electronic Sphygmomanometer, ABPM50
Automatic Blood Pressure Monitor**Apr 28, 2021
219 days to decisionK202757 · Product code: **DXN** · Cardiovascular
Source: <https://www.510kdatabase.net/k202757/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | System, Measurement, Blood-pressure, Non-invasive (DXN) |
| Date received | Sep 21, 2020 |
| Decision date | Apr 28, 2021 |
| Days to decision | 219 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Contec Medical Systems Co.,Ltd |
| Location | Shanghai, CN |
| Contact | Xueyong Li |
| Website | http://www.contecmed.com/ |
| 510(k) history | 12 submissions · 12 cleared · 2011-2024 |

Contec Medical Systems Co., Ltd is a high-tech medical device manufacturer founded in 1996. The company is headquartered in Qinhuangdao, Hebei Province, China, with a manufacturing facility in Shanghai. Contec develops and distributes diagnostic and monitoring devices across multiple therapeutic areas. The company has received FDA 510(k) clearances from total submissions between 2011 and 2024. Contec specializes in cardiovascular devices, including electronic sphygmomanometers, ambulatory blood pressure monitors, and electrocardiographs. The company also manufactures ultr...

REGULATORY CONSULTANT

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|-----------------|---|
| Consulting firm | Beijing Believe-Med Technology Service Co., Ltd. |
| Contact | Ray Wang |

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.net

Device record: <https://www.510kdatabase.net/k202757/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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