FDA 510(k) Premarket Notification

**CLEARED**

# K222153 Microlife Upper Arm Automatic Digital BPM, Model WatchBP Office Vascular (TWIN200 VSR)

Feb 3, 2023
198 days to decision

K222153 · Product code: **DXN** · Cardiovascular
Source: https://www.510kdatabase.net/k222153/

## SUBMISSION DETAILS

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|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | System, Measurement, Blood-pressure, Non-invasive (DXN) |
| Date received | Jul 20, 2022 |
| Decision date | Feb 3, 2023 |
| Days to decision | 198 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

## APPLICANT

| | |
|---|---|
| Company | **Microlife Intellectual Property GmbH** |
| Location | Great Neck, NY, US |
| Contact | Gerhard Frick |
| 510(k) history | 54 submissions · 54 cleared · 2003-2023 |

## REGULATORY CONSULTANT

| | |
|---|---|
| Consulting firm | **Mdi Consultants, Inc.** |
| Contact | Vaibhav Arvind Rajal |

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov