FDA 510(k) Premarket Notification

**CLEARED**

# K193296 eCordum Cardiac Monitor (eCordum CM)

Oct 30, 2020
338 days to decision

K193296 · Product code: **DXH** · Cardiovascular
Source: https://www.510kdatabase.net/k193296/

## SUBMISSION DETAILS

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|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Transmitters And Receivers, Electrocardiograph, Telephone (DXH) |
| Date received | Nov 27, 2019 |
| Decision date | Oct 30, 2020 |
| Days to decision | 338 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

## APPLICANT

| | |
|---|---|
| Company | **Ecordum, Inc.** |
| Location | East Northport, NY, US |
| Contact | Vladislav Bukhman |
| 510(k) history | 1 submissions · 1 cleared · 2020-2020 |

## REGULATORY CONSULTANT

| | |
|---|---|
| Consulting firm | **Biologics Consulting** |
| Contact | Becky Ditty |

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