

K002004 ZYBITSep 21, 2000
80 days to decisionK002004 · Product code: **DXH** · Cardiovascular
Source: <https://www.510kdatabase.net/k002004/>**SUBMISSION DETAILS**

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|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Transmitters And Receivers, Electrocardiograph, Telephone (DXH) |
| Date received | Jul 3, 2000 |
| Decision date | Sep 21, 2000 |
| Days to decision | 80 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Zymed Medical Instrumentation |
| Location | Camarillo, CA, US |
| Contact | GRETEL LUMLEY |
| 510(k) history | 7 submissions · 7 cleared · 1993-2000 |

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