

K811464 MODEL 535-01 TRACE-A-PACE EKG/TELEMETRYSep 23, 1981
120 days to decisionK811464 · Product code: **DXH** · CardiovascularSource: <https://www.510kdatabase.net/k811464/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Transmitters And Receivers, Electrocardiograph, Telephone (DXH)
Date received	May 26, 1981
Decision date	Sep 23, 1981
Days to decision	120 days
Third-party review	No

APPLICANT

Company	Intermedics, Inc.
Location	Mchenry, IL, US
510(k) history	211 submissions · 201 cleared · 1977-1996

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Device record: <https://www.510kdatabase.net/k811464/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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