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MAUDE Adverse Event Report

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TELECTRONICS PACING SYSTEMS OPTIMA MPT 5281 IMPLANTABLE PACEMAKER PULSE GENERATOR

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Model Number 5281

Event Date 08/29/1996

Event Type Malfunction **Patient Outcome** Required Intervention; Other

Manufacturer Narrative

Block f - no user report was received. Sections of block f have been completed by the mfr. Block h3 - failure analysis reveals an internal short caused by tin whisker.

Event Description

Unit was explanted due to a report of a telemetry anomaly. The pacer had exceeded its published longevity by 18 months. Failure analysis confirms the complaint due to an internal short/tin whisker.

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Brand Name	OPTIMA MPT 5281
Type of Device	IMPLANTABLE PACEMAKER PULSE GENERATOR
Manufacturer *(Section D)*	TELECTRONICS PACING SYSTEMS 7400 South Tucson Way Englewood CO 80112
Device Event Key	82489
MDR Report Key	83141
Event Key	78238

Report Number	1316542-1997-00640
Device Sequence Number	1
Product Code	DXY
Report Source	Manufacturer
Source Type	Health Professional,Other
Reporter Occupation	Other
Remedial Action	Recall
Type of Report	Initial
Report Date	03/28/1997
***1* Device Was Involved in the Event**	
***1* Patient Was Involved in the Event**	
Date FDA Received	04/08/1997
Is This An Adverse Event Report?	No
Is This A Product Problem Report?	Yes
Device Operator	Other
Device MODEL Number	5281
Device Catalogue Number	31175
Was Device Available For Evaluation?	Device Returned To Manufacturer
Date Returned to Manufacturer	01/10/1997
Is The Reporter A Health Professional?	No
Was the Report Sent to FDA?	No
Device Age	10 yr
Event Location	Hospital
Date Manufacturer Received	01/17/1997
Was Device Evaluated By Manufacturer?	Yes
Is The Device Single Use?	Yes
Is the Device an Implant?	Yes
Is this an Explanted Device?	
Type of Device Usage	Initial

Removal/Correction Number Z-345/3467

Patient TREATMENT DATA

Date Received: 04/08/1997 Patient Sequence Number: 1

#	Treatment	Treatment Date
1,NA		