TELELECTRONICS PACING SYSTEMS OPTIMA MPT 5281
IMPLANTABLE PACEMAKER PULSE GENERATOR

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.

Search Alerts/Recalls

New Search  |  Submit an Adverse Event Report

Brand Name  OPTIMA MPT 5281
Type of Device IMPLANTABLE PACEMAKER PULSE GENERATOR
Manufacturer (Section D) TELELECTRONICS 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
## Patient TREATMENT DATA

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

<table>
<thead>
<tr>
<th>#</th>
<th>Treatment</th>
<th>Treatment Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>1,NA</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>