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Medical Device Recalls

Class 1 Recall: Guidant Corp. Pacemakers



Date July 18, 2005

**Recall
Initiated:**

Product: The following models of Guidant pacemakers, manufactured between November 25, 1997 and October 26, 2000:

- PULSAR® MAX Models 1170, 1171, 1270
- PULSAR Models 0470, 0870, 0970, 0972, 1172, 1272
- DISCOVERY® Models 1174, 1175, 1273, 1274, 1275
- MERIDIAN® Models 0476, 0976, 1176, 1276
- PULSAR MAX II Models 1180, 1181, 1280
- DISCOVERY II Models 0481, 0981, 1184, 1186, 1187, 1283, 1284, 1285, 1286
- CONTAK TR® Model 1241
- VIRTUS PLUS® II* Models 1380, 1480
- INTELIS II Models 1483, 1484, 1485, 1384, 1385, 1349, 1499

Use: Pacemakers of this type are surgically implanted in persons with a heart disease affecting the heart's ability to generate and conduct electrical impulses. These devices generate small electrical impulses that trigger the heartbeat.

**Recalling
Firm:** Guidant Corporation – CPI Division

4100 Hamline Ave. N.
Saint Paul , Minnesota 55112-5700

**Reason
for
Recall:** A seal within the devices can leak, allowing moisture to affect the electronic circuits. This defect can cause the pacemakers to fail to provide pacing or can cause a rapid heart rate. Other unexpected device behaviors are also possible. The problems may occur without warning and can lead to loss of consciousness, and possibly heart failure and death.

**Public
Contact:** Consumers with questions may contact Guidant Corporation at 1-866-GUIDANT (1-866-484-3268).

**FDA
District:** Minneapolis

**Advice to
Users:**

- If you believe you are pacemaker dependent, contact your physician soon to discuss your treatment options.
- Continue your normal doctor appointments.

- If you experience symptoms of shortness of breath, dizziness, lightheadedness, loss of consciousness, or a prolonged fast heart rate, you should consult with your physician or go to the emergency room immediately.
- If you are not sure which model you have, or if you have other questions regarding your device, consult with your physician.
- If you know your device's model and serial number and want to find out if it is affected by the leakage problem, you can check www.guidant.com/webapp/emarketing/lookup.jsp or contact Guidant Technical Services at 1-866-GUIDANT (1-866-484-3268).

Class I recalls are the most serious type of recall and involve situations in which there is a reasonable probability that use of the product will cause serious injury or death.

For additional information on this product recall, see the Guidant Corporation Web site at: http://www.guidant.com/news/500/web_release/nr_000558.shtml, which includes a copy of the company's notice sent to physicians (http://www.guidant.com/physician_communications/PDM.pdf), and the FDA press release located at: <http://www.fda.gov/bbs/topics/NEWS/2005/NEW01210.html>

Updated July 27, 2005

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