



U.S. Department
of Transportation

**Pipeline and Hazardous
Materials Safety
Administration**

1200 New Jersey Avenue, SE
Washington, D.C. 20590

JUL 22 2008

Mr. Keith Proctor
Terumo Heart Inc.
6180 Jackson Road
Ann Arbor, MI 48103

Ref. No.: 08-0075

Dear Mr. Proctor:

This is in response to your February 26, 2008 letter concerning requirements under the Hazardous Materials Regulations (HMR; 49 CFR Parts 171-180) for design-type testing of lithium-ion batteries. As described in your letter, your company manufactures a medical device powered by a lithium-ion battery pack. The previous design (the S2) has been tested (both the individual cells and the battery pack) in accordance with the UN Manual of Tests and Criteria (tests T1 – T8 contained in section 38.3). Your company is planning on replacing the S2 battery with a new battery (the S3). The S3 cells have successfully passed the UN T1 – T8 tests; however, the battery pack made with S3 cells has not been tested. You ask if you must perform the UN T1 – T8 tests on the battery pack made with the S3 cells.

In your letter you state that the new battery pack will have an increase of equivalent lithium content of 0.144 gram. In accordance with section 38.2 of the UN Manual of Test and Criteria, a change of more than 0.1 gram or 20 percent by mass, whichever is greater, to the cathode, to the anode, or to the electrolyte is considered a new battery. Therefore, the new battery pack described in your letter is subject to the UN T1 – T8 tests. You should also be aware that your batteries as described in your letter are considered “small lithium batteries” under the HMR, and as such are not subject to the UN T1 – T8 testing for domestic transportation until October 1, 2009 (see enclosed Docket HM 224C and HM 224E, published August 9, 2007 (72 FR 44929)).

I hope this information is helpful. If you have further questions, please do not hesitate to contact this office.

Sincerely,

Hattie L. Mitchell
Chief, Regulatory Review and Reinvention
Office of Hazardous Materials Standards

Enclosure

Pollack
 §173.185
 Testing Battery

08-0075

Drakeford, Carolyn <PHMSA>

From: Shelton, Paul <PHMSA>
Sent: Monday, March 17, 2008 3:39 PM
To: Drakeford, Carolyn <PHMSA>
Cc: Singh, Harpreet <PHMSA>
Subject: FW: UN T1 - T8 test requirements

From: Proctor Keith
Sent: Tuesday, February 26, 2008 5:28 PM
To: 'approvals@dot.gov'
Subject: FW: UN T1 - T8 test requirements

To Whom It May Concern,

Terumo Heart, Inc. is a U.S. subsidiary of Terumo Corporation with headquarters and manufacturing facilities in Ann Arbor, Michigan. The company's focus is the innovation and introduction of products to improve the quality of healthcare for heart failure patients. Specifically, Terumo Heart has developed a Left Ventricular Assist Device to provide mechanical circulatory support for patients that have end stage left ventricular failure. A key component of this system is the rechargeable Lithium ion battery packs that are provided to power the implantable pump.

The current product uses a lithium ion cell produced by LG Chemical identified as S2, this cell is being replaced by a similar cell from LG Chemical identified as S3. A copy of the MSDS sheets for both of these battery cells is attached.

The current battery pack utilizes 8 S2 cells arranged in a 2P4S (two parallel four series) configuration. The S3 replacement cells are direct replacements for the S2 cells. There are no changes required for the configuration, protection circuit, housing, or cabling.

The S2 and S3 cells have passed the UN tests T1 - T8 at the cell level. Terumo Heart has also conducted the UN tests T1 - T8 of the S2 battery pack. Our question is whether the UN tests T1 - T8 are required for the S3 battery packs.

The following table provides the Lithium content of the cell and pack for the two configurations.

	Cell Lithium content	Pack Lithium content
S2	0.66 grams	5.28 grams
S3	0.678 grams	5.424 grams
S3-S2	0.018 grams	0.144 grams

There is a 0.144 gram increase in the equivalent lithium content of the S3 battery pack as compared to the S2 battery pack.

Please contact for any additional information requirements.

Sincerely,

Keith Proctor
Director Regulatory Affairs and Quality Systems
Terumo Heart Inc
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Ann Arbor MI 48103

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