



Food and Drug Administration  
10903 New Hampshire Avenue  
Silver Spring, MD 20993

VIA EMAIL & FEDERAL EXPRESS

**FEB 18 2010**

Director of the Consent Decree Compliance Task Force  
Physio-Control, Inc. (Physio-Control)  
11811 Willows Road NE  
Redmond, Washington 98073-9706

Re: U.S. v. Medtronic, Inc. and Physio-Control, Inc., et al., Civ. No. C08-0649

Dear Director:


This letter is issued pursuant to paragraph 4.F. of the Consent Decree of Permanent Injunction (Consent Decree), civil no. 08-CV-0649 (W.D. Wash.), entered by the court on May 9, 2008.

By way of background, the Food and Drug Administration (FDA) received the Third Party Certification dated July 22, 2009, prepared by your expert consultant pursuant to paragraph 4.C. of the Consent Decree and your Notice of Readiness for Reinspection, dated September 29, 2009. Following receipt of these documents, between October 29, 2009, and January 5, 2010, FDA inspected the Physio-Control, Inc. ("Physio"), facilities located at 11811 Willows Road NE, Redmond, Washington, and 3301 Monte Villa Parkway, Suite 230, Bothell, Washington. The purpose of these inspections was to determine whether Physio is operating in conformity with 21 U.S.C. §§ 351(h) and 352(t)(2), 21 C.F.R. Parts 803, 806 and 820, and the Consent Decree in its manufacture of the LIFEPAK 20, LIFEPAK 12, LIFEPAK 500, LIFEPAK 1000, LIFEPAK CR PLUS, LIFEPAK EXPRESS, and any and all components, parts, or accessories thereto, including, but not limited to, the LIFENET Systems, as defined in paragraph 3.C. of the Consent Decree. At the close of the inspection on January 5, 2010, the FDA investigators issued to you a Form FDA 483 List of Inspectional Observations (FDA-483).

Physio submitted a written response to the FDA-483 on January 13, 2010, addressing Observations 1(a) and 1(b). In addition, Physio submitted documents on January 26, 2010, as requested by FDA's Seattle District Office. Your firm had a meeting with the Seattle District Office on January 15, 2010, and with FDA's Center for Devices and Radiological Health on February 4, 2010, to review your FDA-483 response dated January 13, 2010. FDA has reviewed the information provided prior to February 4, 2010, along with the inspectional findings, and has determined that the intended corrections appear adequate. FDA will continue to review the information provided after the February 4, 2010, meeting and if FDA identifies any additional issues, they will need to be addressed by your

firm. Accordingly, pursuant to paragraph 4.F. of the Decree, FDA hereby authorizes Physio-Control, Inc., to resume manufacturing operations of those devices as identified under paragraph 3.C. of the Decree.

Sincerely,

A handwritten signature in black ink, appearing to read "Larry D. Spears for". The signature is fluid and cursive, with a large initial "L" and a stylized "S".

Timothy Ulatowski  
Office Director  
Office of Compliance  
Center for Devices and  
Radiological Health

cc: Mark S. Brown, Esq.