Exhibit 4
Declaration of Joy Lazaroff

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

ELECTRONIC PRIVACY INFORMATION CENTER Plaintiff,	)	
v.	)	Case No. 1:10-cv-1992 (ABJ)
THE UNITED STATES DEPARTMENT OF HOMELAND SECURITY, Defendant.	)	

DECLARATION OF JOY LAZAROFF

I, Joy Lazaroff, hereby declare as follows:

1. My name is Joy B. Lazaroff. I am the Freedom of Information Act ("FOIA") Expert at the Center for Devices and Radiological Health (CDRH), Food and Drug Administration. I have conducted review of CDRH records for public release for over 30 years. FOIA has been my primary program responsibility for over seven years.

2. The statements made in this declaration are based on my personal knowledge, information made available to me in the performance of my official duties, and conclusions reached in accordance therewith.

3. On May 17, 2011, I learned that the Department of Homeland Security ("DHS") received a FOIA request by the Electronic Privacy Information Center ("EPIC") for "[a]ll records concerning TSA tests regarding body scanners and radiation emission or exposure; and "[a]ll records concerning third party tests regarding body scanners and radiation emission or exposure."

4. During its search for records, the Transportation Security Laboratory ("TSL") located, and deemed responsive to the request, a number of records pertaining to federal government testing of the effects of millimeter wave scanners on medical devices.

5. In December, 2009, FDA signed an interagency agreement (IAG) with DHS. The IAG is entitled "Specialized Evaluation of Electromagnetic Compatibility (EMC) of Active Personal Medical Electronic Devices with the Emissions of Advanced Walk-Thru Metal Detectors at Airport Passenger Checkpoints". The IAG has an FDA identification number 224-10-6004 and DHS number HSHQDC-10-X-00495. The purpose of the IAG is for FDA to evaluate the safety of persons using personal medical electronic devices (PMEDs) when they are exposed to emissions from millimeter wave (mmW) scanners used in security screening. At the request of FDA, several manufacturers of implanted and body-worn PMEDs have voluntarily participated in this program and loaned their devices to FDA for testing. All scanners were provided to FDA by DHS.

6. Upon preliminary review, TSL identified a subset of those records that could potentially contain confidential commercial information submitted by vendors of medical devices. Because of FDA's expertise in the subject matter, and its role in oversight of the testing program, FDA was consulted to determine whether, in fact, any of the material at issue was subject to FOIA Exemption 4, which shields from disclosure "trade secrets and commercial or financial information obtained from a person [that is] privileged or confidential." 5 U.S.C. § 552(b)(4).

7. The records at issue pertained to Medtronic, a manufacturer of medical devices. After an initial review, FDA conducted the "submitter notice" process, pursuant to Executive

Order 12600, to notify Medtronic and provide it with an opportunity to identify any information it believed to be exempt from disclosure.

8. Medtronic identified such information in two records. These records have been released in part at TSL28 and TSL613-623.

9. The document at TSL28 is a letter sent by Medtronic to Schiphol Airport in the Netherlands in 2007. The letter was submitted by L-3 Communications, a millimeter wave scanner manufacturer, to FDA and DHS in 2010 in connection with the testing of the effects of its millimeter wave scanners on medical devices pursuant to the inter-agency agreement described above.

10. The document at TSL613-623 is a test proposal submitted by Medtronic to FDA in 2010 that outlines proposed steps for testing the effects of millimeter wave scanners on Medtronic medical devices pursuant to the inter-agency agreement. The document is marked "MEDTRONIC CONFIDENTIAL."

11. Neither of the documents at issue was required to be submitted to the government by Medtronic. Medtronic was not required to participate in the scanner testing program or submit any related documentation in order to participate in the program. To conduct this testing program, FDA asked manufacturers of medical devices to voluntarily loan devices and provide documents such as these to FDA to help determine if there are safety issues resulting from interaction of emissions from mmW scanners with implanted and body worn medical devices.

12. Pursuant to the submitter notice process, Medtronic requested that portions of these documents be withheld under Exemption 4 of FOIA. The withheld portions in TSL28 contain Medtronic's own findings regarding the interaction between the L3 Provision 100 scanner and Medtronic medical devices. The withheld portions in TSL613-23 contain details

regarding Medtronic's plan for testing the interaction of emissions from mmW scanners with Medtronic devices, along with the model names of those devices.

13. Medtronic has represented that the withheld portions contain information that Medtronic would not customarily disclose to the public. I have reviewed the withholdings and, based on over 30 years of experience reviewing CDRH records to ensure compliance with applicable disclosure laws, I have no reason to dispute Medtronic's representations and agree that the withheld portions generally contain the type of information not customarily disclosed by companies in this industry.

14. Accordingly, these portions are being withheld under Exemption 4 of FOIA as "commercial or financial information obtained from a person [that is] privileged or confidential."

Pursuant to 28 U.S.C. § 1746, I declare under penalty of perjury that the foregoing is true and correct.

Executed on: September 9, 2011

Joy B. Lazaroff