



Health  
Canada

Santé  
Canada

Health Products  
and Food Branch

Direction générale des produits  
de santé et des aliments

Medical Devices Bureau  
2934 Baseline Road  
3rd Floor, Tower B  
Qualicum  
**Address Locator: 3403A**  
OTTAWA, Ontario K1A 0K9

September 30, 2013.

Neill Moroney  
CEO  
A Major Difference Inc.  
7318 South Revere Parkway, Suite B-7  
Centennial, CO  
US, 80012

Dear Mr. Moroney:

In the absence of specific medical/therapeutic claims, ion detoxification devices are generally not considered to fit the definition of a medical device as outlined in the *Food & Drugs Act* and *Medical Devices Regulations*. Based on the most current Operating Instruction manuals that were provided for The IonCleanse Solo and the IonCleanse Premier, neither system is marketed as a device that is intended to diagnose, treat, mitigate or prevent a particular disease or abnormal physical condition. The devices in question are represented for use as general “wellness” products and therefore, do not fit the definition of a medical device.

Yours sincerely,

Colin Foster  
Senior Regulatory Information Officer  
Medical Devices Bureau