Health Canada Santé Canada

Therapeutic Products Directorate
Room 1605, Main Building
150 Tunney's Pasture Driveway
Tunney's Pasture, A.L. 0301H1
Ottawa ON K1A 0K9

October 20, 2010

John Bethune
[redacted]
USA
[redacted]

Re: Device Classification

Dear Mr. Bethune:

This is in reference to your request of September 30, 2010 for a letter confirming the classification of the [redacted], ampoule opener, [redacted], and [redacted].

As stated previously in my e-mail ruling of August 13, 2010, these four products do not meet the definition of a medical device and therefore are not subject to the *Medical Devices Regulations*.

The *Food and Drugs Act* defines "device" as "any article, instrument, apparatus or contrivance, including any component, part or accessory thereof, manufactured, sold or represented for use in

(a) the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state, or its symptoms, in human beings or animals,
(b) restoring, correcting or modifying a body function or the body structure of human beings or animals,
(c) the diagnosis of pregnancy in human beings or animals, or
(d) the care of human beings or animals during pregnancy and at and after birth of the offspring, including care of the offspring,
and includes a contraceptive device but does not include a drug"

A "medical device" is defined as "a device within the meaning of the Act, but does not include any device that is intended for use in relation to animals."

If you have any questions please do not hesitate to contact me.

Sincerely,

Daniel Yoon
Regulatory Information Officer
Medical Devices Bureau
Tel: 613-941-2181