DEVICE CLASSIFICATION

Taken From Annex IX MDD 93/42/EEC

Classification Criteria

Duration		
Transient: Normally intended for continuous use for less than 60 minutes.	Y	
Short term: Normally intended for continuous use for not more than 30 days.		N
Long term: Normally intended for continuous use for more than 30 days.		N
Active medical device Rule 10 ;The Microstim DB3 transmits electrical energy to the patient	Y	
Non-invasive device	Y	
Invasive device		N
Implantable device		N
Reusable surgical instrument		N
Active therapeutical device		N
Active device for diagnosis		N

Implementing the rules

1. Application of the classification rules shall be governed by the intended purpose of the devices.
2. If the device is intended to be used in combination with another device, the classification rules shall apply separately to each of the devices. Accessories are classified in their own right separately from the device with which they are used.
3. Software, which drives a device or influences the use of a device, falls automatically in the same class.
4. If the device is not intended to be used solely or principally in a specific part of the body, it must be considered and classified on the basis of the most critical specified use.
5. If several rules apply to the same device, based on the performance specified for the device by the manufacturer, the strictest rules resulting in the higher classification shall apply.

III. CLASSIFICATION

The device is classified as Class IIa

CMDR DEVICE CLASSIFICATION

Taken From Health Canada MDA Schedule 1

Invasive Devices		N	Rule	Classification
Active Device	Y		Rule 9	Classification
Special Rules		N	Rule	Classification
In Vitro Diagnostic Device		N	Rule	Classification
Other Uses		N	Rule	Classification
Special Rules		N	Rule	Classification

The device is classified as Class II

Classified J.S Lamb 05/09/08