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Canada

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**Re: Expanded Use Authorization**

This letter is in reference to the expanded use of the indications for use for the **DOLPHIN NEUROSTIM**, currently authorized for sale according to the *Medical Devices Regulations* (Medical Device Licence number 67326).

The new indication for expanded use are as follows:

Dolphin Vagal Nerve Stimulator (VNS) is authorized for emergency use in the acute treatment of adult patients with known or suspected COVID-19. Intended for those who are experiencing exacerbation of asthma-related dyspnea and reduced airflow, and for whom approved drug therapies are not tolerated or provide insufficient symptom relief as assessed by their healthcare provider, using non-invasive VNS applied to the auricular branch of the vagus nerve (ABVN) during the COVID-19 pandemic can help with symptom relief.

Sincerely,

David Boudreau, ing.  
Director General  
Medical Devices Directorate  
Health Products and Food Branch  
Health Canada

DB/bc

cc: A. Nguyen, ROEB  
B. Dowling, MDD