Health Canada Santé Canada

Medical Devices Bureau
11 Holland Ave.
Ottawa, Ontario K1A 0K9
Address Locator: 3005B

December 5, 2018

Joanne Charlebois
Chief Executive Officer
Speech-Language and Audiology Canada
amy@sac-oac.ca

Dear Ms. Charlebois:

Thank you for your letter dated December 3, 2018 in which you expressed concerns about the impact of the Medical Device Single Audit Program (MDSAP) on the availability of medical devices in Canada. We understand your concerns and would like to provide you with information regarding potential alternative devices.

The transition from the Canadian Medical Devices Conformity Assessment System (CMDCAS) to MDSAP is not new to the industry and a long transition time was provided. It was announced in January of 2015 with an effective date of January 1, 2019 (i.e. 4 years). MDSAP moves us away from a Canada-only program to one that is in line with other major markets, using the same ISO standard.

The decision to transition, or not, to MDSAP is a business decision. That being said, rest assured that Health Canada closely monitors the transition to MDSAP. More specifically, the Medical Devices Bureau (MDB) is monitoring potential risks and challenges that could arise from some manufacturers choosing to exit the Canadian market, in order to ensure access to safe and effective medical devices in Canada. We are prepared to take action should issues be identified that represent a significant risk to Canadians and the healthcare system.

It is unfortunate that the manufacturers of the devices listed in your correspondence have elected not to transition to MDSAP, and as a consequence will no longer be in a position to sell their products in Canada as of January 1, 2019. We understand that this will have an impact on your organization and your patients.

We have reviewed the list of devices you provided in your correspondence. I would note that the Servox Electrolarynx is a Class I device, and as such, it is not subject to the quality system requirements (i.e. MDSAP is not required for Class I devices). Class I devices can be obtained from any distributor or importer that

holds a Medical Device Establishment Licence (MDEL) for that device. Additional information about MDEL can be found at https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/establishment-licences.html.

Should the other three medical devices mentioned in your letter no longer be available for sale in Canada, you can search for potential alternative licensed devices on the Medical Devices Active Licence Listing (MDALL) at any time. The MDALL database lists all licensed medical devices in Canada and is available to the public at https://health-products.canada.ca/mdall-limh/index-eng.jsp.
For your convenience, we have performed a search and identified a few potential alternative medical device licences for the Passy-Muir Tracheostomy Speaking Valve and the Fahl Laryngectomy Tube for your consideration (see tables below).

Passy-Muir Tracheostomy Speaking Valve alternatives

Licence no.	Licence name	Device ID	Device name
8607	Montgomery Speaking Valves	143673	Montgomery Speaking Valves
1845	Shiley Phonate Speaking Valve	182822 182823	Shiley Phonate Speaking Valve Shiley Phonate Speaking Valve (With Oxygen Port)
94766	TRACOE Phon Assist II Speaking Valves REF 655-S AND REF 655-T With Attachable Tracoe Humid Assist II REF 645	804032 1001469	Tracoe Humid Assist II Tracoe Phon Assist II Speaking Valves

Fahl Laryngectomy Tube alternatives

Licence no.	Licence name	Device ID	Device name
18744	Singer Laryngectomy Tube	SLT-0818 to SLT-1655	Singer Laryngectomy Tube - Silicone
6897	Blom-singer Laryngectomy Tubes	BE629F-BE6305F BE6298-BE6305	Blom-Singer Fenestrated Laryngectomy Tube, Non-Sterile Blom-Singer Laryngectomy Tube, Non-Sterile

		BE6398- BE6405	Blom-Singer Laryngectomy Tube, Non-Sterile

Please note that the patient population and duration of use was not specifically mentioned in the intended use statement for the above licences. You may want to perform additional research to ensure that these devices would meet your requirements. In addition, any changes related to the treatment plan of a patient should be reviewed and approved by a Health Care Professional.

Should none of the potential alternative devices listed above be appropriate, patient specific requests might qualify for access to the through the Medical Devices Special Access Programme (SAP).

In the case of the Iowa Oral Performance Instrument, this does appear to be a unique product and patient specific requests for access to this device may also be eligible for access via the SAP.

The SAP allows physicians to legally gain access to medical devices that are not licenced for sale in Canada. Special access to medical devices is requested in cases of emergency or when conventional therapies have failed, are unavailable or are unsuitable to treat a patient. Please note that where potential licenced alternative exist, any SAP application for a specific device would have to include a rationale explaining why all the other licenced devices are unsuitable to treat a specific patient. Please note that SAP requests may only be submitted by a physician. Once SAP authorization is granted by Health Canada, the manufacturer may sell the device to the physician. Decisions for such requests are made on a case-by-case basis.

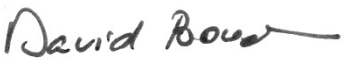
Information on the SAP for medical devices, as well as the guidance document about the requirements and the application form for a physician to make a request, can be found at https://www.canada.ca/en/health-canada/services/drugs-health-products/special-access/medical-devices.html

Should you wish to obtain additional information or if you would like to contact the Special Access Program directly, they can be reached at 613-946-8711or hc.sap.devices.mdb.sc@canada.ca.

I trust that this information will provide you with alternative solutions should the manufacturers decide to no longer offer their products in Canada. If you have any further questions about medical device licensing, please feel free to contact the Medical Devices Bureau at 613-957-7285 or hc.mdb.enquiries-enquetes.bmm.sc@canada.ca.

Thank you for writing.

Sincerely,



David Boudreau, ing.
Executive Director
Medical Devices Bureau