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MEMORANDUM **NOTE DE SERVICE**

TO Rosslynn Miller-Lee
Executive Director,
Medical Device Evaluation Bureau
MDD

FROM Patrice Sarrazin
DE IVD Device Evaluation Division
MDD

SUBJECT Recommendation for Authorization under Interim Order
OBJET Manufacturer: **Spartan Bioscience**

Device: Spartan COVID-19 System (application #313012)

Background

On March 26, 2020, Health Canada received an application from Spartan Biosience seeking authorization for sale for the Spartan COVID-19 System. The system is composed of the Spartan CUBE instrument and the Spartan COVID-19 assay intended for the detection of SARS-CoV-2 in oropharyngeal samples in laboratory and point of care settings. None of the component is currently licensed in Canada.

This application was submitted under the Interim Order Respecting the Importation and Sale of Medical Devices for Use in Relation to COVID-19 pursuant to subsection 30.1(1) of the Food and Drugs Act. This Interim Order is allowing the Department to issue expedited authorization for sale or import of medical devices to deal with the current significant risk of COVID-19 to the health and safety of Canadians.

The information submitted is currently evaluated based on the *Policy for Diagnostics Tests for Coronavirus Disease 2019 during the Public Health Emergency* guidance issued by the US FDA on March 16, 2020, and on the *EUA Interactive Review Template for Molecular-Based Tests for SARS-CoV-2 That Causes COVID-19* issued by the US FDA on March 12, 2020. The requirements described in the Interim Order (IO) are also being evaluated.

As of March 26, 2020, the Spartan COVID-19 System ***was not*** submitted to the US FDA for Emergency Use Authorization (EUA).

On March 24, 2020, it was established by the Medical Devices Directorate's management (David Boudreau, MDD Director General) that in the absence of information validating the performance of the assay to detect SARS-CoV-2, Health Canada will issue an authorization under the Medical Devices Interim Order, with a condition that the sale or import of the product is to be for research use only until such time as Spartan provides to

Health Canada the necessary evidence validating the effectiveness of their device, and Health Canada removes this condition.

Intended Use (final intended use statement to be provided)

"The Spartan Cube is a sample-to-result platform that integrates sample extraction, nucleic acid amplification, fluorescence detection, and automated results interpretation. An oropharyngeal sample is collected using Spartan's proprietary swab. The swab tip is inserted into a proprietary test cartridge. Inside the cartridge, RNA from viral particles undergoes reverse transcription followed by PCR amplification (RT-PCR); the amplified DNA is detected by fluorescent probes; the fluorescence signal is detected by an optical system and algorithms analyze the signal and interpret the results."

Discussion:

To support the safety and effectiveness of the assay, Spartan Bioscience submitted a preliminary submission to support the cross-reactivity and inclusivity of the test based on the COVID-19 primers and probes published by the Center for Disease Control and Prevention (CDC). This information is currently under review. Additional validation studies supporting the limit of detection and the clinical performance of the assay are expected to be submitted to Health Canada for review by April 2, 2020.

This conditional authorization will allow Spartan Bioscience to import the Spartan CUBE instruments manufactured in China.

It has been established by the Medical Devices Directorate's management (David Boudreau, MDD Director General) that in the absence of a final decision confirming that the test can detect SARS-CoV-2, it is recommended to issue an authorization under the Medical Devices Interim Order to authorize the importation of the Spartan COVID-19 System, with a condition that the Spartan COVID-19 System is to be used for research use only until such time as Health Canada assesses the documentation submitted by Spartan Bioscience. If the safety and effectiveness of the test are adequately supported, this condition will be removed by Health Canada.

RECOMMENDATION:

Authorization of the Spartan COVID-19 System under the Interim Order with the following condition:

1. No distribution of the Spartan COVID-19 System is authorized until such time as Health Canada assesses the documentation to be submitted by Spartan and removes this condition.

2. The Spartan COVID-19 System is authorized for Research Use Only until such time as Health Canada assesses the documentation to be submitted by Spartan and removes this condition.

3. Spartan Bioscience shall submit evidence supporting the intended use of the Spartan COVID-19 System.

I concur / Je suis d'accord

	2020-03-26		
Patrice Sarrazin In Vitro Diagnostic Section / Matériels diagnostiques in vitro Device Evaluation Division / Division de l'Évaluation des Matériels	Date	**Rosslyn Miller-Lee** Executive Director/ Directrice Executive Medical Devices Evaluation Bureau/ Bureau de l'évaluation des instruments médicaux	Date