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MEMORANDUM **NOTE DE SERVICE**

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

FROM Emily Hollink
DE MDD

SUBJECT Recommendation for Authorization under the COVID-19 Interim Order
OBJET Manufacturer: Spartan Bioscience Inc.

Device: Spartan COVID-19 System
Application: 313012

Background

The application for the Spartan COVID-19 System was reviewed under the Interim Order Respecting the Importation and Sale of Medical Devices for Use in Relation to COVID-19. This Interim Order will allow 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 was evaluated based on the Medical Devices Regulations and the "*Emergency Use Authorization Interactive Review Template for Molecular-Based Tests for SARS-CoV-2 that causes Coronavirus disease 2019 (COVID-19)*" issued by the US FDA (Version March 12, 2020).

This will be the first regulatory authorization for the Spartan COVID-19 System.

Intended Use

The Spartan COVID-19 System is intended for the qualitative detection of nucleic acids from SARS-CoV-2, obtained from a nasal or oropharyngeal swab sample collected from individuals suspected of COVID-19 that meet the SARS-CoV-2 clinical criteria.

The SARS-CoV-2 nucleic acids are generally detectable in oropharyngeal or nasal swabs during the acute phase of infection. Positive results are indicative of an active infection with SARS-CoV-2; clinical correlation with patient history and other diagnostic information is necessary to determine patient infection status. Positive results do not rule out bacterial infection or co-infection with other viruses. Testing facilities within Canada are required to report all positive results to the appropriate public health authorities.

Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for patient management decisions. Negative results must be combined with clinical observations, patient history, and epidemiological information.

The Spartan COVID-19 test is intended for use by medical professionals or trained operators.

[Spartan COVID-19 System Instructions for Use; CUS-00064_1.0 04/2020]

Discussion: The information provided meets the minimum requirements to authorize the Spartan COVID-19 System under Interim Order, with several studies to be completed and submitted post-authorization.

The Spartan COVID-19 test uses proprietary PCR technology that includes sample collection with their device (included), and then analyte extraction and analysis in one step, thus offering a simple solution for a more complex laboratory method. Analytical and contrived clinical studies were performed in silico or with the use of purified RNA in the intended sample matrices. Reagent stability data is based on a similar licensed product, and the stability protocol has been provided.

The labelling has been revised to meet Health Canada requirements, and meets the minimum requirements of both the Regulations and the additional COVID-19 related labeling information outlined in the EUA FDA template.

Based on the scientific evidence available, it is reasonable that the product will be effective for the claimed intended use. In the current context related to the COVID-19 pandemic, the risks related to the use of this assay are outweighed by the benefits associated with increased PCR testing capacity at remote or rural locations. Furthermore, and consistent with Good Laboratory Practices, the National Microbiological Laboratory intends to validate and use this device. A post-market authorization condition has been included to ensure the performance with clinical samples in the field is consistent with pre-market data submitted.

RECOMMENDATION:

Previously, the Spartan COVID-19 System was authorized 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.

Authorization of the Spartan COVID-19 System under Interim Order is now recommended with the following revised conditions:

Within one month:

1. Provide a sample stability study evaluating the ability of the sample to withstand storage for longer than 5 minutes prior to running the test.

2. Perform an endogenous interference study evaluating 1% v/v blood and 0.5% w/v mucin in the process as a whole, including the viral RNA extraction process.

When available:

3. Provide, when available, the shelf-life study results. The shelf life should evaluate the ability of the test to perform all steps, including the RNA extraction.

Every three months:

4. Provide a report that includes a list of the countries where the device is sold, the number of assays and instruments sold in those countries; and the number of complaints and the resolution category.

[signed in email]		I concur / Je suis d'accord	
	2020-04-11		
Emily Hollink	Date	**Rosslyn Miller-Lee** Executive Director/ Directrice Executive Medical Devices Evaluation Bureau/ Bureau de l'évaluation des instruments médicaux	Date