Government of Canada
MEMORANDUM

Gouvernement du Canada
NOTE DE SERVICE

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

FROM
DE Emily Hollink
MDD

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

Device: Spartan COVID-19 System
IO Application: 313012
ITA Application: 315695

Background

A regulatory authorization, with conditions, for the Spartan COVID-19 System was issued on March 26, 2020. These conditions were modified on April 11, 2020, and again on May 1, 2020. The conditions require that Spartan submit an application for an Investigational Testing Authorization, as well as studies of sample stability and analytical specificity.

On May 13, 2020, an application for an Investigational Testing Authorization was submitted. In addition, on May 15, 2020, information was provided to respond to two conditions that addressed sample stability and analytical specificity.

Discussion:

Investigational Testing Authorization Application

Consistent with the condition requirement, an application for an Investigational Testing Authorization (ITA) was received. On May 15, 2020, a screening deficiency letter was issued to seek substantial additional information to support the application.

The ITA application included use of a new formulation, thus the manufacturer was informed that comprehensive pre-clinical data would be required. In addition, the protocol design required clarification and potential revision, as the overall application lacked detail to understand if the design of the swab had been modified.

This application described a study that would be the equivalent of a Phase I (early) clinical trial, thus additional clinical data would need to be collected after the completion of this study, if authorized, to support the device Interim Order authorization.

It is recommended that the condition pertaining to the clinical trial (condition #3) be revised to acknowledge that an application has been received but that further clinical studies will be required.

Conditions for preclinical studies

Studies that assess analytical specificity in the presence of specific substances (blood and mucin); and stability of the indicated specimens over a 24 hour period were provided. The demonstrated performance is acceptable. As such, it is recommended that the conditions for these preclinical studies (conditions #4 and 5) have been fulfilled and may be removed from the authorization.

RECOMMENDATION:

Previously, the Spartan COVID-19 System was authorized under the Interim Order with the following conditions:

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. Within one month, Spartan Bioscience shall submit an investigational testing (clinical trial) application to Health Canada to obtain clinical evidence to support the intended use of the Spartan COVID-19 System. The clinical trial shall assess all aspects of the Spartan COVID-19 System, including the sampling method and proprietary swab.

   The first two conditions will not be modified until sufficient clinical information is provided to support the intended use of the Spartan COVID-19 System, and is deemed by Health Canada to be acceptable.

Modified from previous authorization:

Within two weeks:

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

5. 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:

6. 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.

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

1. The Spartan COVID-19 System is authorized for Research Use Only.

2. No distribution of the Spartan COVID-19 System is authorized, other than for research purposes.

3. Spartan Bioscience shall continue the application process to conduct a clinical trial to support the intended use of the Spartan COVID-19 System. The clinical trial shall assess all aspects of the Spartan COVID-19 System, including the sampling method and proprietary swab.

   The first two conditions will not be modified until sufficient clinical information is provided to support the intended use of the Spartan COVID-19 System, and is deemed by Health Canada to be acceptable.

When available:

4. 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.

[signed in docuBridge]		I concur / Je suis d'accord	
	2020-05-22		
Emily Hollink	Date	**Rosslyn Miller-Lee** Executive Director/ Directrice Executive Medical Devices Evaluation Bureau/ Bureau de l'évaluation des instruments médicaux	Date