Health Canada / Santé Canada

CONSOLIDATED SCREENING FORM MEDICAL DEVICES

Application Information

Application #:	Licence Name:	Application Type:	Device Class:
312781 Licence #: **0**	**NXTAG COV EXTENDED PANEL**		**3**
Manufacturer: **LUMINEX MOLECULAR DIAGNOSTICS, INC.**		Company ID: **0**	

DLSD Application Validation

Risk Class & Rule:	Licence Type & Rationale:	Special Substances:
Class III, IVDD Rule 2[b]i	Test Kit	

Amendment Management

Fee Category:	Reason for Amendment:

Bundle Information

Bundle Rationale:	Related Applications Bundle table included?	Create/Modify Financial Bundle Info
	☐	

Submission Completeness

MDR	Requirement	A	D	N/A	Notes/Comments
32	Application Form	☑	☐	☐	Did not include io authorization request form, instead included a document with the information (information request form)
32	Submission Presentation (ToC, Cover Letter, Exec Summary)	☑	☐	☐	
32(3a/4a)	Device Description (as it relates to device listing in form)	☑	☐	☐	
32(3j/4p)	QMS Certificate MDSAP/CSA-ISO 13485:2016	☐	☐	☑	
32(3g/4o)	Labelling – 21(1a)(1b)(1c)	☐	☑	☐	Device identifier is not included in the IFU and the manufacturer did not provide device labels.

DLSD Recommendation

Incomple

Notes/Comments:

- The manufacturer did not list a device identifier in their Information Request Form
- The manufacturer did not provide product package labels, and the IFU does not contain device identifiers therefore the device identifiers are not currently known
- Quality Attestations were not provided (4(1)(i))
- The address was not provided where the device will be manufactured (4(1)(d)
- Section 4(2)(a) of the Interim Order was not included (description of materials and packaging)

Emily Smalling

Device Licensing Services Division
Medical Devices Bureau

Date:
Mar. 19, 2020

Review Division – DLSD Communication

Review Division Screener Action:

Review Division Screener Response:

Health Canada / Santé Canada

CONSOLIDATED SCREENING FORM
MEDICAL DEVICES

Review Division Screener Medical Devices Bureau	Date:

Health Canada Santé Canada

CONSOLIDATED SCREENING FORM
MEDICAL DEVICES

Technical Screening (Review Division)

Proposed reviewer:	Estimated Review Time (days):	Review Complexity:

Review Components	Review Required	Deficient	Comments
Class III + IV			
General Application Organization		☐	
Device Description	☐	☐	
Marketing History	☐	☐	
Standards & Conformity Declaration	☐	☐	
Analytical Performance	☐	☐	
Physical & Chemical Bench Testing	☐	☐	
Electrical & Radiation Safety	☐	☐	
Software Validation & Verification	☐	☐	
Biocompatibility & Pyrogenicity	☐	☐	
Sterilization, Packaging, &Shelf Life	☐	☐	
Animal Testing	☐	☐	
Stability	☐	☐	
Product Stability (Shelf Life)	☐	☐	
Usability	☐	☐	
Clinical Studies	☐	☐	
Bibliography	☐	☐	
Near patient IVDD	☐	☐	
Labelling	☐	☐	
Class IV			
Risk Assessment	☐	☐	
Quality Plan	☐	☐	
Biological Safety	☐	☐	
Manufacturing Process	☐	☐	
Process Validation	☐	☐	

Note to the Reviewer (e.g. predicate, reference, cautions, directions) ☐ Foreign Review incl. ☐ SBD?

Recommendation

Bundle Update/Modification – **To DLS manager** ☐

Technical Screening Deficiencies:

1. _____

_____ _____

DLSD Deficiencies	
☐ **Over Paid Fee Deficiency**	
1.	

COVID-19 Medical Device & Manufacturer Details	
Class of Device	III
Intended Use of Device (Section 4(1)(f))	The Luminex NxTAG® CoV Extended Panel is intended for use on the Luminex® MAGPIX® instrument for the qualitative detection of nucleic acid from the 2019-nCoV in nasopharyngeal swabs collected from individuals with signs and symptoms of infection who are suspected of COVID-19.

Device Name	Identifier	GMDN Code	PNC Code
NxTAG® CoV Extended Panel		64747	88UJH