



Class III In Vitro Diagnostic Device Licence Evaluation Report

Administrative Information

<i>Application Information</i>			
Application number	Licence Name	Licence Number	Risk Class
Application Type	Licence Type	Manufacturer	Company ID

<i>Scientific Review Information</i>		
Reviewed by	Review Division:	Review Division Manager:
Date Review Assigned: Click here to enter a date.	Date Review Completed: Click here to enter a date.	

This report contains Confidential Business Information (CBI) that should be redacted: Yes/No



***Class III In Vitro Diagnostic Device Licence
Evaluation Report***

1 Background Information

Application Bundle Information	
Primary Application	
Secondary Applications	

1.1 Indications and/or Intended Use, and Contraindications

This application includes changes to device indications: Yes/No

Reviewer's Discussion

1.2 Device Description

1.2.1 General Description

Reviewer's Discussion

1.2.2 Modifications

Reviewer's Discussion

1.3 Design Philosophy

Reviewer's Discussion



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1.4 Marketing History/Regulatory Status

1.4.1 Canadian

This device has been released via SAP: Yes/No

This device has been authorised via ITA: Yes/No

Reviewer's Discussion

1.4.2 International

Reviewer's Discussion

1.4.3 Incident Reports

Reviewer's Discussion

1.5 Manufacturing site

Reviewer's Discussion

2 Safety and Effectiveness Studies

2.1 List of standards

Reviewer's Discussion



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2.2 Software Verification and Validation

Version Tested:

Reviewer's Discussion

2.3 Preclinical studies

Reviewer's Discussion

2.4 Stability Studies

Reviewer's Discussion

2.5 Clinical studies

Reviewer's Discussion

2.6 Near Patient Investigational Testing

Reviewer's Discussion

2.7 Bibliography



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3 Labelling/Packaging

3.1 Labels & Package Insert

Reviewer's Discussion

3.2 Packaging

Reviewer's Discussion

3.3 Limitations and Warnings

Reviewer's Discussion

4 Conclusion

[Start/Review Quality Report Card \(You will need to click OK in the popup after clicking here\)](#)

[Note: Changes cannot be made once the feedback results are concurred by SH.](#)

5 Recommendation

Acceptance for licensing

Acceptance of the following amendments:

Acceptance with the following conditions:

Refusal:

Request for additional information:

DO NOT DELETE – Ensure recommendation falls above this line

Application no.

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GRP TMP_0003 v6.4