



Class IV In Vitro 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

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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

2 Manufacturing and Quality Control

2.1 Manufacturing site

Reviewer's Discussion

2.2 Material Specifications

Reviewer's Discussion



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2.3 Manufacturing Process

Reviewer's Discussion

2.4 Process Validation Studies

2.4.1 Sterilization & Re-sterilization Validation

Reviewer's Discussion

2.5 Quality Control Activities

Reviewer's Discussion

3 Safety and Effectiveness Studies

3.1 List of standards

Reviewer's Discussion

3.2 Software Verification and Validation

Version Tested:

Reviewer's Discussion

3.3 Preclinical studies

Application no.

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GRP TMP_004 v6.5



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Reviewer's Discussion

3.4 Stability Studies

Reviewer's Discussion:

3.5 Clinical studies

Reviewer's Discussion

3.6 Near Patient Investigational Testing

Reviewer's Discussion

3.7 Literature Studies & Bibliography

4 Risk Assessment

Reviewer's Discussion

5 Labelling/Packaging

5.1 Labels & Package Insert

Reviewer's Discussion

Application no.



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5.2 Packaging

Reviewer's Discussion

5.3 Limitations and Warnings

Reviewer's Discussion

6 Conclusions

[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.](#)

7 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