Health Canada Santé Canada

Class IV In Vitro Device Licence Evaluation Report

Administrative Information

Application Information			
Application number	Licence Name	Licence Number	Risk Class
Application Type	Licence Type	Manufacturer	Company ID

Scientific Review Information		
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

Health Canada Santé Canada

Class IV In Vitro Device Licence Evaluation Report

Contents

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

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

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

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

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