GLP REPORT

TEST FACILITY

NAMSA
6750 Wales Road
Northwood, OH 43619
419.666.9455

SPONSOR

Kambiz Tajkarimi
Reflexonic, LLC
5504 Skye Avenue
Chambersburg, PA 17202

CONFIDENTIAL

STUDY TITLE

Cytotoxicity Study Using the ISO Agarose Overlay Method - Solid

TEST ARTICLE NAME

Viberect Pad Overmold

TEST ARTICLE IDENTIFICATION

Pad Overmold

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Summary

The test article, Viberect Pad Overmold, was evaluated to determine the potential for cytotoxicity based on the requirements of ISO 10993-5: Biological Evaluation of Medical Devices – Part 5: Tests for *In Vitro* Cytotoxicity. Triplicate wells were dosed with a 1 cm x 1 cm portion of the test article. Triplicate wells were dosed with a 1 cm length of high density polyethylene as a negative control. Triplicate wells were dosed with a 1 cm x 1 cm portion of latex as a positive control. Each was placed on an agarose surface directly overlaying a subconfluent monolayer of L-929 mouse fibroblast cells. After incubating at 37°C in the presence of 5% CO_2 for 24 hours, the cultures were examined macroscopically and microscopically for any abnormal cell morphology and cell lysis.

The test article showed no evidence of causing any cell lysis or toxicity. The test article met the requirements of the test since the grade was less than a grade 2 (mild reactivity).

Supervisory Personnel:

Melissa A. Cadaret, B.A., M.S.
Manager, Toxicology

Austin M. Zdawczyk, B.S., M.B.A., ALAT
Supervisor, In Vitro

Approved by:

Jennifer N. Moritz, B.S.
Study Director

4/28/11
Date Completed

Statement of GLP Compliance

This study was conducted in accordance with the provisions of the FDA Good Laboratory Practice (GLP) Regulations (21 CFR, Part 58).

Study Director: Jennifer N. Moritz, B.S. 4-28-11 Date

1. Introduction

Purpose
The purpose of this study was to determine the potential of the test article to cause cytotoxicity.

Testing Guidelines
This study was based on the requirements of the International Organization for Standardization 10993-5: Biological Evaluation of Medical Devices - Part 5: Tests for *In Vitro* Cytotoxicity.

Dates

Test Article Received:	March 23, 2011
Cells Dosed:	April 26, 2011
Observations Concluded:	April 27, 2011

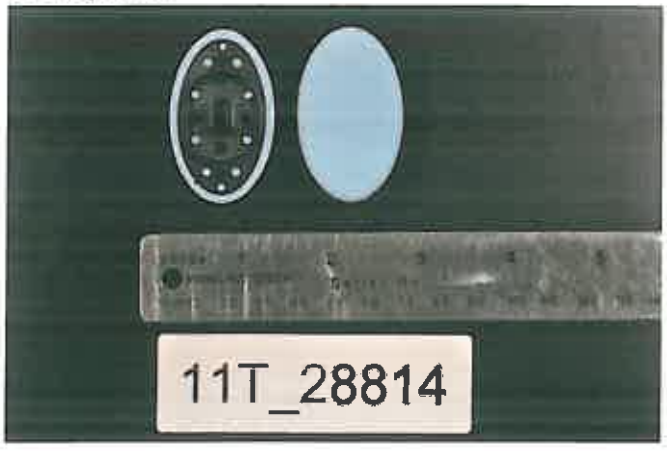
GLP Compliance
The study initiated by protocol signature on April 13, 2011 was conducted in accordance with the provisions of the FDA Good Laboratory Practice (GLP) Regulations, 21 CFR 58. A Statement of Quality Assurance Activities was issued with this report.

2. Materials

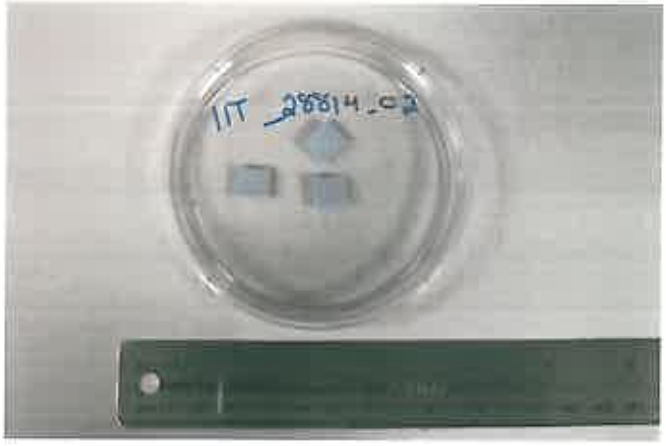
The test article provided by the sponsor was identified and handled as follows:

Test Article Name:	Viberect Pad Overmold
Identification:	Pad Overmold
Stability Testing:	In progress (per sponsor)
Expiration Date:	Stable for duration of intended testing (per sponsor)
Strength, Purity and Composition:	Strength: not applicable because no active ingredients are used to formulate a concentration Purity: not applicable because the test article is a multi-component device
	Composition: Irogran A85P4394 thermoplastic polyurethane elastomer
Physical Description of the Test Article:	Pad overmold (blue) thermoplastic polyurethane for skin contact (penis) for vibratory nerve stimulation. Black is to be removed and discarded.
Storage Conditions:	Room Temperature

Pre-Preparation



Post-Preparation



Negative Control Article:	High density polyethylene (HDPE)
Stability Testing:	Marketed product; stability characterized by its labeling
Strength, Purity, Composition or Other Characteristics:	Purity: Meets USP <661> Polyethylene Containers, Multiple Internal Reflectance, Thermal Analysis, Heavy Metals, and Non-Volatile Residue; Composition: Neat CAS #: 9002-88-4
Positive Control Article:	Latex
Stability Testing:	Marketed product; stability characterized by its labeling
Strength, Purity, Composition or Other Characteristics:	Composition: natural rubber latex, zinc carbamate accelerators, zinc oxide, and titanium dioxide
Growth Media:	Single strength Minimum Essential Medium supplemented with 5% fetal bovine serum, 2% antibiotics (100 units/mL penicillin, 100 µg/mL streptomycin, and 2.5 µg/mL amphotericin B) and 1% (2 mM) L-glutamine (1X MEM)
	Double strength Minimum Essential Medium supplemented with 10% fetal bovine serum, 4% antibiotics (200 units/mL peniciillin, 200 µg/mL streptomycin and 5.0 µg/mL amphotericin B) and 2% (4 mM) L-glutamine (2X MEM)
Test Article Preparation:	The black plastic component was removed and excluded from testing. Only the blue pad overmold was tested. The smooth side of the blue pad overmold was tested against the agar. Triplicate wells were dosed with a 1 cm x 1 cm portion of the test article.
Negative Control Preparation:	Triplicate wells were dosed with a 1 cm length of HDPE.
Positive Control Preparation:	Triplicate wells were dosed with a 1 cm x 1 cm portion of latex.

3. Test System

Test System and Justification of Test System
Mammalian cell culture monolayers consisting of L-929 mouse fibroblast cells (ECACC Cat# 85103115, or equivalent source) were used. *In vitro* mammalian cell culture studies have been used historically to evaluate cytotoxicity of biomaterials and medical devices.

Test System Management
L-929 mouse fibroblast cells were propagated and maintained in 1X MEM at 37°C with 5% carbon dioxide (CO_2). For this study, cells were seeded in 10 cm^2 wells and incubated at 37°C in the presence of 5% CO_2 to obtain subconfluent monolayers of cells prior to use. Aseptic procedures were used in the handling of the cell cultures following approved NAMSA Standard Operating Procedures.

Preparation of Agarose Overlay
The culture wells were selected which contained a sub-confluent cell monolayer. The agarose mixture was prepared with equal amounts of 2% agarose and 2X MEM supplemented with neutral red. The growth medium in each well was replaced with 2.0 mL of the agarose mixture. The agarose mixture was allowed to solidify over the cells to form the agarose overlay.

4. Method

The prepared test article was placed on the solidified agarose surface in each of three cell culture wells. Similarly, the negative control and the positive control were each placed on the solidified agarose surface in three cell culture wells. The wells were labeled with the corresponding lab number and dosing date, and incubated at 37°C in the presence of 5% CO_2 for 24 hours.

Following incubation, the cultures were examined macroscopically for cell decolorization around the test article and controls to determine the zone of cell lysis (if any). After macroscopic examination, the cell monolayers were examined microscopically (100X) to verify any decolorized zones and to determine cell morphology in proximity to the article. Scoring for cytotoxicity was based on the following criteria:

Grade	Reactivity	Condition of Cultures
0	None	No detectable zone around or under specimen
1	Slight	Some malformed or degenerated cells under specimen
2	Mild	Zone limited to area under specimen
3	Moderate	Zone extending specimen size up to 1.0 cm
4	Severe	Zone extending farther than 1.0 cm beyond specimen

For the suitability of the system to be confirmed, the negative control must have been a grade of 0 (reactivity none) and the positive control must have been a grade equal to or greater than a grade of 3 (reactivity moderate to severe). The test article passed the test if all three monolayers were less than or equal to a grade of 2 (reactivity mild).

All times and temperatures reported herein are approximate and are within ranges established by the external standards described in the References section of this report and/or NAMSA standard operating procedures.

5. Results

The scores obtained were as follows:

Articles		Zone of Lysis (mm)	Grade	Reactivity
Test Article:	(1)	0	0	None
	(2)	0	0	None
	(3)	0	0	None
Negative Control:	(1)	0	0	None
	(2)	0	0	None
	(3)	0	0	None
Positive Control:	(1)	8	3	Moderate
	(2)	8	3	Moderate
	(3)	8	3	Moderate

6. Conclusion

The test article showed no evidence of causing any cell lysis or toxicity. The test article met the requirements of the test since the grade was less than or equal to a grade 2 (mild reactivity).

Results and conclusions apply only to the test article tested. Any extrapolation of these data to other articles is the sponsor's responsibility.

7. Quality Assurance

Inspections were conducted at intervals adequate to assure the integrity of the study in conformance with 21 CFR 58.35(b)(3). The final report was reviewed for conformance to Section 58.185, Subpart J, of the GLP Regulations. A Statement of Quality Assurance Activities was issued with the report.

8. Records

All raw data pertaining to this study and a copy of the final report are to be retained in designated NAMSA archive files.

9. ISO Compliance

All procedures were certified to ISO 13485:2003 and accredited to ISO 17025:2005.

10. References

Code of Federal Regulations (CFR), Title 21, Part 58, Good Laboratory Practice for Nonclinical Laboratory Studies.

International Organization for Standardization (ISO) 10993-5, Biological Evaluation of Medical Devices - Part 5: Tests for *In Vitro* Cytotoxicity (2009).

United States Pharmacopeia 32, National Formulary 27 (USP), General Chapter <87>, Biological Reactivity Tests, In Vitro (2009).

International Organization for Standardization (ISO) 13485, Medical Devices - Quality Management Systems - Requirements for Regulatory Purposes (2003).

International Organization for Standardization (ISO) 17025, General Requirements for the Competence of Testing and Calibration Laboratories (2005).

Statement of Quality Assurance Activities

Phase Inspected	Date Inspected	Date Reported to Study Director	Date Reported to Management
Dosing	April 26, 2011	April 26, 2011	April 26, 2011
Study Data Review	April 27, 2011	April 27, 2011	April 27, 2011
Final Report Review	April 28, 2011	April 28, 2011	April 28, 2011

Based on a review of this study, it has been concluded that this report accurately describes the methods and standard operating procedures, and that the reported results accurately reflect the raw data of the study. This study has been reviewed in accordance with the provisions of the FDA Good Laboratory Practice Regulations (21 CFR, Part 58).

QA Representative: Marie Glodowski 4-28-11

Marie Glodowski, B.S.
Auditor, Quality Assurance

Date