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STUDY N° 71217
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Preclinical & Clinical Evaluation of Medical Devices

Confidential

Research Services

FINAL REPORT

CYTOTOXICITY STUDY USING THE ISO 10993 STANDARD WITH EXTRACT ON THE MANDIBULAR ADVANCEMENT DEVICE SOMNOLIS, REFERENCE SLC-01, BATCH 270208

Consulting Services

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Histopathological Services

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SUMMARY

An *In vitro* biocompatibility test on the Mandibular advancement device SOMNOLIS, reference SLC-01, batch 270208 was conducted to evaluate the potential for cytotoxicity. This study was conducted according to the requirements of the ISO 10993 standard: Biological Evaluation of Medical Devices, Part 5 (1999): Tests for *in vitro* cytotoxicity. An extract of the test article was prepared as follows:

- Extraction vehicle	:	Minimum Essential Medium Eagle 1X (EMEM 1X) supplemented with L-glutamine 1 % (v/v), foetal bovine serum 10 % (v/v) and antibiotics (penicillin – streptomycin 2 % (v/v))
- Temperature	:	37°C + or - 1°C
- Duration	:	24-26 hours with agitation
- Ratio test article/vehicle	:	3 cm^2/mL

This test extract was placed onto triplicate confluent monolayers of L-929 mouse fibroblast cells. Separate monolayers were prepared for triplicate negative and positive controls. After incubating at 37 ± 1°C in 5 ± 1 % CO_2 for 24-26 hours, the cell cultures were stained by a neutral red solution and examined microscopically (at least 100X) to determine cell morphology. The dye was then extracted from the cultures and optical density was measured at 550 nm.

Under the conditions of this study, the extract of the test article showed no cytotoxicity with a mean percentage of cell reduction of –7.3 %. The negative and positive controls performed as anticipated.

This study has been conducted in accordance with the GLP FDA requirements described in the 21 CFR 58 (revised as of April 1st, 2007) and in accordance with the requirements of the OECD Good Laboratory Practices, reference ENV/MC/CHEM(98) 17, adopted by Council on November 26th, 1997.

Report approved by : Date : April 18, 2008

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