Nelson Labs™
A Sotera Health company

Sponsor:
Baumer A/S
Runetoften 19
8210 Aarhus Denmark

NELSON LABS, EUROPE
USP Class VI

Summary: Enclosed is the final report for the testing we coordinated for you. The information is retained by the testing laboratory.

Test Article:	Peek tip for CleverLevel
Assigned NLE Lab Number:	18-03060-N2
Testing Facility:	Toxikon Corporation
LOT Number:	11108652

Sample Preparation & Chain of Custody Statement: The biocompatibility test articles were received at Nelson Labs Europe and assigned a project number. The test articles were then shipped to the Nelson Laboratories, LLC Salt Lake City facility where they received an official assigned Nelson assigned Laboratory Number/s and tested.

If you have any questions, please feel free to call or email any of our Subcontracting personnel at 003216400484. Thank you for testing with Nelson Labs Europe.

Customer Support — Cindy Claes

18 Sep 2018
Date

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TEST RESULT CERTIFICATE

Sponsor	Nelson Laboratories, NV	**Technical Initiation**	8/16/2018
Address	Romeinsestraat 12 Leuven, Belgium B-3001	**Technical Completion**	8/31/2018
Contact	Cindy Claes, Juli Messinger	**Report Date**	9/17/2018
P.O. Number	TE181818	**Final Non-GLP Report**	18-03060-N2

Test Article	PEEK tip for CleverLevel (11108652)	**Ratio**	3 cm^2/mL
CAS/Code	Not Supplied by Sponsor (N/S)	**Vehicles**	USP 0.9% Sodium Chloride for Injection (NaCl), Cottonseed Oil (CSO), 1 in 20 Ethanol in NaCl (EtOH), and Polyethylene Glycol 400 (PEG)
Lot/Batch #	N/S		
Physical State	Solid		
Color	Tan		
Sterility:	Not Sterile		
Storage Conditions	Room Temperature		
Study	Class VI Test – USP	**Extraction Conditions**	50 ± 2 °C for 72 ± 2 hours
Comments	Nelson Lab Number: 1084027		

REFERENCES:

The study was conducted based upon the following references:

United States Pharmacopeia 41, National Formulary 36, 2018. <88> Biological Reactivity Tests, *In Vivo*.

ISO/IEC 17025, 2017, General Requirements for the Competence of Testing and Calibration Laboratories.

GENERAL PROCEDURE:

The extraction conditions were performed as stated above. The test article extracts and corresponding blanks were injected systemically and intracutaneously in mice and rabbits, respectively. The injections were in the amounts and routes set forth by USP, including the further dilution of the extracts prepared with PEG. The animals were observed for signs of toxicity and skin reactivity for up to 72 hours post treatment. In addition, the test article was implanted into the paravertebral muscles of rabbits for 7 days and observed macroscopically for signs of hemorrhage, necrosis, discoloration, encapsulation, and infection.

RESULTS AND CONCLUSION:

None of the mice injected with the test article extracts exhibited any signs of toxicity in the Systemic Injection Test. In addition, none of the rabbits injected intracutaneously with the test article extracts exhibited any signs of erythema, edema, or clinical toxicity. In both the Systemic and Intracutaneous Tests, the controls were normal through 72 hours. Also, the implant sites exhibited no significant signs of hemorrhage, necrosis, discoloration, encapsulation, or infection compared with the control sites.

The test article meets the requirements of the guidelines for the Biological Test for Plastics, Class VI – 50°C.

AUTHORIZED PERSONNEL:

Dena D. Hoeun, B.S.
Quality Assurance

D. Radhika
Radhika Devalaraja, Ph.D.
Study Director