

uPhoria V&V Test Data 20170104
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THE SPONSOR HAS RELEASED THE SYSTEM AND CHEMISTRY FOR USE AS DIRECTED. THE DESIGN HISTORY FILE HAS THE COMPLETED SAFETY RISK ASSESSMENT. RISK FROM USE, REASONABLE MIS-USE, AND OVERALL PRODUCT RISK EXIST.

Validation Study	Study Directive	SUMMARY	RESULTS	DATA
Enamel Micro-Hardness	ISO28399 Report_EPP 15-217 20150922.pdf	See below	Passed	Improved hardness w uPhoria vs 2000% worse with Citric Acid
Enamel Erosion (loss)	ISO28399 Report_EPP 15-217 20150922.pdf	See below	Passed	NO 'Enamel Loss' w uPhoria vs 15um loss with Citric Acid
Safety testing	IEC 60601-1 A-ProDev-v3_CE-SafetyTestReport_CMG7922-4 20151125.pdf	Verification of system according to the following sections of IEC 60601: > Radiated Immunity > Leakage Current & Patient Immunity	Passed; The product fulfils the requirements of EN60601-1, 3rd edition	Safety and essential performance are verified, with NO evaluation of Safety Risk Assessment. Sponsor cites equivalence to existing systems and therapies available currently.
Soft Tissue test	Epigivival erosion test; EpiGingivalTestReport_7439-IIVS-Final_20131231.pdf	Substantially equivalent. Test article Gel formula represented a worse case formula relative to uPhoria treatment Gel.	Not inferior; Passed	...the addition of the ultrasonic device to the test article treatment does not increase oral/buccal irritation levels
Efficacy	Independent testing - Validation: A-ProDev_UsabilityValidationProtocol_v3.1.pdf	Sample size: N=35; 23 patients met inclusion criteria. Dentists, hygienists and patients.	Passed	Average whitening effect of 4 minute treatment: 4.52 shades
Life Testing	Independent testing - In vitro Verification	System tested for 8064 cycles	Passed	12.9 YEARS WITHOUT FAILURE; assumes - 2 per day, 6 days per week, total of 624 treatments per year.
Safety Risk Assessment	ISO 14970, & CFR 21, Part 872 SRA_ProDev-V2_Risk_Worksheet-r2.2.pdf	Hazards of the uPhoria whitening treatment system for adults provided by a trained dentist to whiten discolored natural teeth are qualified.	Risk (system) - Acceptable Overall Risk - Acceptable	The Overall Risk Assessment of hazards have been found to be reduced to an acceptable level.