510(k) Summary for FUSION Plus Curing Lights

K180065

1. APPLICANT

DentLight Inc.
1825 Summit Ave., Suite 210
Plano, TX 75074

Phone: 972-889-8857
Fax: 972-346-6550
Contact Person: Richard Liu

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2. DEVICE NAME

Proprietary Name: FUSION Plus Curing Light

Common/Usual Name: Dental Curing Light

Classification Name: Ultraviolet activator for polymerization (872.6070)

Product Code: EBZ

3. PRIMARY PREDICATE DEVICE

Valo (K083647), manufactured by Ultradent Products, Inc

REFERENCE DEVICE

FUSION (K052593), manufactured by DentLight Inc.

4. INTENDED USE / INDICATIONS FOR USE

Source of illumination for curing photo-activated dental restorative materials and adhesives.

5. DEVICE DESCRIPTION

Fusion Plus Curing Light is a portable dental LED curing light system. It provides a source of illumination for polymerization of photo-activated dental materials. The principle of operation is the same as the predicate devices: illumination for polymerization or curing of photo-activated dental materials. It uses our patented Fusion optical technology in combination with high-power LED to deliver high efficiency and high-power curing light.

The system consists of a curing handpiece, a charging stand, 100 barrier sleeves, light shields, a power adapter, and instructions for use. The handpiece is constructed of aluminum and consists of a main control, a light head, and a rechargeable battery assembly. The main control houses the control circuitry with microprocessor and user interface consisting of LCD display and two control buttons. A mode button selects operation timer and two curing modes: plasma or pulse mode. A ON/OFF button activates and deactivates the light. The handpiece is non-sterile utilizing the barrier sleeves for infection control. Similar to the predicate devices, the light shield and curing cap absorb emitted light

and perform the function of eye protection. The charging stand allows for the placement of the handpiece in a holder with electrical connection to the power adapter as the source for charging the rechargeable battery. FUSION Plus has an interchangeable LED light head. Depending on the light head connected with the main control or added later, the kit can be configured in three options:

Trade Name	**LED Peak Wavelength (nm)**
FUSION Plus	395-480
FUSION Plus Standard	440-480

The instructions for use detail the use of each head in curing of dental materials.

6. DEVICE CHARACTERISTICS AND SUBSTANDTIAL EQUIVALENCE

FUSION Plus is substantially equivalent to the predicate device Valo (K083647) manufactured by Ultradent Products Inc. and FUSION (K052593) designed and manufactured by DentLight Inc. A comparison table with the predicate and reference devices lists key features and characteristics of the subject and predicate devices. It shows the product to be substantially equivalent to the predicate devices.

Parameter		**FUSION Plus**	**Valo (Primary Predicate Device)**	**FUSION (Reference Device)**
Indications for Use		Source of illumination for curing photo-activated dental restorative materials and adhesives	Source of illumination for curing photo-activated dental restorative materials and adhesives	Photopolymerization of dental resins, restorative composite materials, and orthodontic brackets, bonding, and sealing that are photo-polymerized in the 440-480nm wavelength range
510(k) Number		K180065	K083647	K052593
Product Code		EBZ	EBZ	EBZ
Regulation Number		21 CFR 872.6070	21 CFR 872.6070	21 CFR 872.6070
Device Class		II	II	II
Common Name of Classification		Ultraviolet activator for polymerization	Ultraviolet activator for polymerization	Ultraviolet activator for polymerization
Light Source		High-power LED	High-power LED	High-power LED
Power Supply		Input: 100-240V - 50/60Hz; Output: 5V 1-2A	Input: 100-240VAC@50-60Hz; Output: 12V 5A	Input: 100-240V - 50/60Hz; Output: 5V 1-2A
Peak Wavelength Range		395-480 (Plus head)	395-480 nm	440-480 nm
		440-480 nm (Plus Standard)		
Curing Optical Intensity mW/cm^2	Plasma	4000	4500	2700
	Pulse/high	2000	1400	1350
	Standard	NA	1000	NA
User Control Interface		2 Buttons	2 Buttons	2 Buttons
Weight (grams)		112	75 grams	111
Battery		Lithium ion	NA	Lithium ion
Structure		Ergonomic wand	Ergonomic wand	Ergonomic wand
Materials		Aluminum body, plastic barrier control and light shield	Aluminum body, plastic barrier control and light shield	Aluminum body, plastic barrier control and light shield
Compliance Standards		IEC 60601-1; IEC 60601-1-2	IEC 60601-1; IEC 60601-1-2	IEC 60601-1; IEC 60601-1-2

Similarities between the FUSION Plus Curing Light and Valo:

- The FUSION Plus has the same indications for use as the primary predicate device Valo.
- The FUSION Plus has substantially equivalent curing modes as the primary predicate device Valo.
- The FUSION Plus has substantially equivalent performance characteristics as the primary predicate device Valo.
- The FUSION Plus is substantially equivalent to the primary predicate device Valo in standards compliance.

Differences between the FUSION Plus Curing Light and Valo:

The primary predicate Valo has a uni-body construction with a fixed aluminum body. The FUSION Plus has a modular aluminum body construction with a swivel interchangeable light head: Plus Head and Plus Standard Head. The Plus Head has a wavelength range of 395- 480nm that is the same as the primary predicate Valo and wider than the reference device FUSION. These wavelengths cover VLC materials with photoinitiator sensitive to all photoactivated dental materials (395- 480nm). The difference in construction improves the operator's ease of use and does not raise any substantial equivalence concerns as it has the same wavelengths of the primary predicate Valo.

Similarities between the FUSION Plus Curing Light and the reference device FUSION:

- The FUSION Plus and the reference device FUSION has the same construction. FUSION Plus Standard Head has the same center wavelengths of 440 nm – 480 nm as the reference device FUSION. The wavelengths cover VLC materials with photoinitiators sensitive to photoactivated dental materials in the 440 nm – 480 nm (CQ and PPD).
- The FUSION Plus and the reference device FUSION use the same optoelctronic design, FUSION optical beam technology, and construction materials except the Plus Head LED.

Both FUSION Plus head and FUSION Plus Standard head are powered and controlled by the same main control under the same condition with the only difference being the choice of LED and its placement. These differences do not raise concerns about safety and effectiveness as the performances are similar to the primary predicate device and the reference device.

7. NON-CLINICAL PERFORMANCE TESTING

The following non-clinical tests were conducted to evaluate the functionality, performance, safety, and substantial equivalence of the FUSION Plus Curing Light to the predicate device as suggested by the FDA's guidance for industry and FDA staff titled "Dental Curing Lights – Premarket Notification [510(k)] Submissions" issued on March 27, 2006:

- device performance
  - optical irradiance
  - spectral irradiance
  - curing time
  - curing modes and safety controls
  - heat management
- software and hardware verification and validation,
- risks to health and traceability analysis
- electrical safety and electromagnetic compatibility

FUSION Plus complies with the electrical and optical safety requirements as the predicate devices: IEC 60601-1, IEC 60601-1-2, and ANSI/ADA 48-2.

8. CONCLUSION

Based on similarities in indications for use and technology together with results from performance testing, we believe that FUSION Plus Curing Light is substantially equivalent to the predicate devices.