December 22, 2023

SharpLight Technologies Ltd
Rada Trifonov
RA Manager
33 Lazarov St
Rishon Le Zion, 7565435
Israel

Re: K233304
Trade/Device Name: Omnimax S3, Omnimax S4
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: Class II
Product Code: GEX, GEI, NUV, ONG, ONE, ONF
Dated: September 29, 2023
Received: September 29, 2023

Dear Rada Trifonov:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Shlomit Halachmi -S

Digitally signed by Shlomit Halachmi -S
Date: 2023.12.22 06:43:50 -05'00'

For

Tanisha Hithe
Assistant Director
DHT4A: Division of General Surgery Devices

OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K233304

Device Name
Omnimax Device Series

Indications for Use *(Describe)*
The Omnimax Device Series along with its optional Handpieces, uses IPL, IR, Laser and RF technologies and is intended for use in aesthetic and cosmetic applications and in selective treatments in medical specialties of dermatology, through the transmission of energy to human skin.

Intense Pulsed Light (IPL-DPC) with 415 – 1200 nm wavelengths (with and without contact-cooling) handpieces are indicated for:
* Hair removal and Permanent Hair Reduction in all skin types (I-V) to the Fitzpatrick scale - Recommended wavelengths in the range of 635-950 nm, 730-950 nm or 580-950 nm. * Flow Mode is suitable for Fitzpatrick skin types I-VI. Recommended wavelength: 635nm-950nm.
* Treatment of Benign Pigmented Epidermal and Cutaneous Lesions including warts, scars and striae in all skin types (I-VI) to the Fitzpatrick scale - Recommended wavelength in the range of 580-950 nm.
* Treatment of Pigmented and Vascular Lesions in all skin types (I-VI) to the Fitzpatrick scale – Recommended wavelength in the range of 535-950 nm.
* Treatment of Benign Pigmented Epidermal, Cutaneous and Vascular Lesions including warts; scars and striae in skin types (I-V) to the Fitzpatrick scale – Recommended wavelength in the range of 535-680 nm & 860-1200nm.
* Treatment of Inflammatory Acne (acne vulgaris) in skin types (I-V) to the Fitzpatrick scale – Recommended wavelength in the range of 415-950 nm.
Infrared (IR) with 850 – 1750 nm wavelengths (with contact cooling) handpieces is indicated for:
* Dermatologic Treatment such as, but not limited to: photocoagulation of soft tissue (Scars, Wrinkles, Rhytids and Periorbital Wrinkles).

Radio Frequency (RF) handpieces are indicated for:
* Treatment of mild to moderate facial wrinkles and rhytids for all skin types.

Nd:YAG Laser 1064 nm Long Pulse (LP) handpiece is indicated for:
* Removal of unwanted hair, for stable long-term, or permanent, hair reduction through selective targeting of melanin in hair follicles.
* Removal or lightening of unwanted hair.
* Treatment of pseudofolliculitis barbae (PFB).
* Benign vascular lesions such as, but not limited to treatment of: Port wine stains; Hemangiomas; Warts, Superficial and deep telangiectasias (venulectasias); Reticular veins (0.1-4.0 mm dia.) of the leg; Rosacea; Venus lake; Leg veins; Spider veins; Poikiloderma of Civatte; Angiomas.
* Benign cutaneous lesions, such as, but not limited to: Warts; Scars; Striae; Psoriasis.
* Benign pigmented lesions such as, but not limited to: Lentigos (age spots); Solar lentigos (sun spots); Cafe-au-lait macules; Seborrheic; keratoses; Nevi and nevus of Ota, Chloasma; Verrucae; Skin tags; Keratoses; Plaques.
* Pigmented lesions to reduce lesion size, for patients with lesions that would potentially benefit from aggressive treatment and for patients with lesions that have not responded to other laser treatments.
* The non-ablative treatment of facial wrinkles, such as, but not limited to: Periocular wrinkles; Perioral wrinkles.
* Laser skin resurfacing procedures for the treatment of: Acne scars; Wrinkles.
* Reduction of red pigmentation in hypertrophic and keloid scars where vascularity is an integral part of the scar.
* Indicated for use on all skin types (Fitzpatrick I-VI).

Nd:YAG 1064 nm Q-Switched Laser with optional 532 nm Frequency Doubler (FD) handpiece indicated for:
* The removal of black, blue or green tattoos (significant reduction in the intensity of black and /or blue/black tattoos);
* Tattoo removal: Light blue; Yellow; Red; Green. * Benign pigmented lesions, such as, but not limited to: Cafe-au-lait (macules); Lentigines (senile and solar); Freckles (ephelides); Chloasma; Nevi; Nevus spillus, Nevus of Ota; Becker's Nevi.
* Other pigmented cutaneous lesions, such as, but not limited to: Verrucae; Skin tags; Keratoses; Plaques.

Er:YAG Laser 2940 nm Long Pulse (LP), with standard and scanner accessory tips handpiece is indicated for:
* Use in soft tissue (skin, cutaneous tissue, subcutaneous tissue) for Skin resurfacing; Treatment of wrinkles; Epidermal nevi; Telangiectasia; Spider veins; Actinic chelitis; Keloids; Verrucae; Skin tags; Anal tags; Keratoses; Scar revision (including acne scars).

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510K Summary

Applicant Information

Applicant Information	SharpLight Technologies Ltd. 33 Lazarov St. Rishon Le Zion 7565435, Israel Tel: (972) 3-961-1969 Fax: (972) 3-952-8890
Contact Person	Rada Trifonov 33 Lazarov St. Rishon Le Zion 7565435, Israel Tel: (972)- 547797218
Date Prepared	September 29, 2023
Device Common Name	Omnimax Device Series

Classification

Product Code	Primary GEX, Secondary GEI, NUV, ONG, ONE, ONF
Regulation No.	21 CFR § 878.4810
Class	II
Panel	General & Plastic Surgery
Regulation Description	Laser Surgical Instrument, for use in General and Plastic Surgery and Dermatology

Identification of Legally Marketed Predicate Devices

SharpLight – Dermatological Treatment Device Family	K111303
Pollogen – Apollo System	K111026

Device Description

The Omnimax Device Series, which includes the Omnimax S3 and S4 devices, is a multi-application, multi-technology platform designed for skin treatments and various aesthetic and dermatological applications. This is achieved by applying light energy (IPL, IR, and Laser) and Radio Frequency (RF) to the human skin. Each device in the series features the following technologies:

The Omnimax S4 incorporates IPL-DPC, IR, RF, and Laser technologies.
The Omnimax S3 incorporates IPL-DPC, IR, and RF technologies.

The Omnimax Device Series modification enhances capabilities of the legally cleared Dermatological Treatment Device Family (K111303) by adding RF functionality with optional handpieces in addition to the previously cleared IPL, Laser and IR technology.
The system consists of:

a) Main unit (includes controller)
b) Control Panel (UI)
c) RF Module
d) Display Unit
e) Footswitch
f) Trolley
g) 14 Handpieces/applicators:
    - IPL-DPC – 7 Handpieces
    - IR – 2 Handpieces
    - Laser – 3 Handpieces
    - RF – 2 Handpieces

The main unit is a platform system with embedded software, designed to support all treatment technologies and handpieces (i.e. IPL-DPC, IR, Laser and RF).

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Intended Use

The Omnimax Device Series along with its optional Handpieces, uses IPL, IR, Laser and RF technologies and is intended for use in aesthetic and cosmetic applications and in selective treatments in medical specialties of dermatology, through the transmission of energy to human skin.

Indications for use and patient population

Intense Pulsed Light (IPL-DPC) with 415 – 1200 nm wavelengths (with and without contact-cooling) handpieces are indicated for:

* Hair removal and Permanent Hair Reduction in all skin types (I-V) to the Fitzpatrick scale - Recommended wavelengths in the range of 635-950 nm, 730-950 nm or 580-950 nm.
* Flow Mode is suitable for Fitzpatrick skin types I-VI. Recommended wavelength: 635nm-950nm.
* Treatment of Benign Pigmented Epidermal and Cutaneous Lesions including warts, scars and striae in all skin types (I-VI) to the Fitzpatrick scale - Recommended wavelength in the range of 580-950 nm.

* Treatment of Pigmented and Vascular Lesions in all skin types (I-VI) to the Fitzpatrick scale – Recommended wavelength in the range of 535-950 nm.

* Treatment of Benign Pigmented Epidermal, Cutaneous and Vascular Lesions including warts; scars and striae in skin types (I-V) to the Fitzpatrick scale – Recommended wavelength in the range of 535-680 nm & 860-1200nm.

* Treatment of Inflammatory Acne (acne vulgaris) in skin types (I-V) to the Fitzpatrick scale – Recommended wavelength in the range of 415-950 nm.

Infrared (IR) with 850 – 1750 nm wavelengths (with contact cooling) handpieces is indicated for:

* Dermatologic Treatment such as, but not limited to: photocoagulation of soft tissue (Scars, Wrinkles, Rhytids and Periorbital Wrinkles).

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Radio Frequency (RF) handpieces are indicated for:

* Treatment of mild to moderate facial wrinkles and rhytids for all skin types.

Nd:YAG Laser 1064 nm Long Pulse (LP) handpiece is indicated for:

* Removal of unwanted hair, for stable long-term, or permanent, hair reduction through selective targeting of melanin in hair follicles.

* Removal or lightening of unwanted hair.
* Treatment of pseudofolliculitis barbae (PFB).

* Benign vascular lesions such as, but not limited to treatment of: Port wine stains; Hemangiomas; Warts, Superficial and deep telangiectasias (venulectasias); Reticular veins (0.1-4.0 mm dia.) of the leg; Rosacea; Venus lake; Leg veins; Spider veins; Poikiloderma of Civatte; Angiomas.
* Benign cutaneous lesions, such as, but not limited to: Warts; Scars; Striae; Psoriasis.
* Benign pigmented lesions such as, but not limited to: Lentigos (age spots); Solar lentigos (sun spots); Cafe-au-lait macules; Seborrheic; keratoses; Nevi and nevus of Ota, Chloasma; Verrucae; Skin tags; Keratoses; Plaques.
* Pigmented lesions to reduce lesion size, for patients with lesions that would potentially benefit from aggressive treatment and for patients with lesions that have not responded to other laser treatments.
* The non-ablative treatment of facial wrinkles, such as, but not limited to: Periocular wrinkles; Perioral wrinkles.
* Laser skin resurfacing procedures for the treatment of: Acne scars; Wrinkles.
* Reduction of red pigmentation in hypertrophic and keloid scars where vascularity is an integral part of the scar.

* Indicated for use on all skin types (Fitzpatrick I-VI).

Nd:YAG 1064 nm Q-Switched Laser with optional 532 nm Frequency Doubler (FD) handpiece indicated for:

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* The removal of black, blue or green tattoos (significant reduction in the intensity of black and /or blue/black tattoos);

* Tattoo removal: Light blue; Yellow; Red; Green.

* Benign pigmented lesions, such as, but not limited to: Cafe-au-lait (macules); Lentigines (senile and solar); Freckles (ephelides); Chloasma; Nevi; Nevus spillus, Nevus of Ota; Becker's Nevi.

* Other pigmented cutaneous lesions, such as, but not limited to: Verrucae; Skin tags; Keratoses; Plaques.

Er:YAG Laser 2940 nm Long Pulse (LP), with standard and scanner accessory tips handpiece is indicated for:

* Use in soft tissue (skin, cutaneous tissue, subcutaneous tissue) for Skin resurfacing; Treatment of wrinkles; Epidermal nevi; Telangiectasia; Spider veins; Actinic chelitis; Keloids; Verrucae; Skin tags; Anal tags; Keratoses; Scar revision (including acne scars).

Technological Characteristics

The Omnimax Device Series shares the same intended use and indications for IPL, IR, Laser and RF technologies as its predicate devices. Furthermore, the technological characteristics and operational principles of the Omnimax Device Series align with those of the predicate devices.

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Comparison table of the technological characteristics is provided as follows:

	Proposed Device		Predicate 1	Predicate 2	Characteristic Comparison (same/different)
Common Device Name	**Omnimax Series Device Family (Trade name: Omnimax S3, Omnimax S4)**		**Dermatologic Treatment System Device family**	**Apollo System**	N/A
Manufacturer	Sharplight Technologies Ltd.		Sharplight Technologies Ltd.	Pollogen Ltd.	
510(k) Number	TBD		K111303	K111026	
Device Class	Class II		Class II	Class II	Same
Classification Panel	General and Plastic Surgery		General and Plastic Surgery	General and Plastic Surgery	Same
Product code	GEX, GEI		GEX	GEI	Same per technology
Device main components	h) Main unit (includes controller) i) Control Panel (UI) j) RF Unit k) Display Unit l) Footswitch m) Trolley n) 14 handpieces/applicators: ▪ IPL-DPC – 7 ▪ IR – 2 ▪ Laser – 3 ▪ RF – 2 handpieces		a) Main unit (includes controller) b) Control Panel (UI) c) Display Unit d) Footswitch e) Trolley f) 12 handpieces/applicators: ▪ IPL-DPC – 7 ▪ IR – 2 ▪ Laser – 3	a) Main Unit (includes controller) b) Control Panel (UI) c) RF Unit d) Footswitch e) Patient Controlled Manual Switch f) 3 handpieces/ applicators: g) RF – 3 (2 of which are being compared)	Same per technology
Supported technologies	IPL-DPC, IR, Laser, RF		IPL-DPC, IR, Laser	RF	Same per technology
Wavelength Spectrum	**IPL-DPC**	415 – 1200 nm	415 – 1200 nm	N/A	Same
	IR	850 - 1750 nm	850 - 1750 nm		Same

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	Proposed Device		Predicate 1	Predicate 2	Characteristic Comparison (same/different)
	ER:Yag Laser 2940	2940 nm	2940 nm		Same
	Nd:Yag LP Laser	1064 nm	1064 nm		Same
	Q-Switched Laser	532 and 1064 nm	532 and 1064 nm		Same
Fluence/ Power	**IPL-DPC**	5 - 25 J/cm^2	5 - 30 J/cm^2	N/A	Same, within predicate 1 limits
	IR	15 - 60 J/cm^2	5 - 80 J/cm^2		Same, within predicate 1 limits
	ER:Yag Laser 2940	0.2-2.6 J	0.2J-1.2 J		Same lower limit, different upper limit, no impact on safety or efficacy
	Nd:Yag LP Laser	30 - 350 J/cm^2	30 - 450 J/cm^2		Same, within predicate 1 limits
	Q-Switched Laser	0.4-1.4 J	0.2-1.2 J		Different, no impact on safety or efficacy
	RF	Up to 50 W	N/A	Up to 50 W	Same

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	Proposed Device		Predicate 1	Predicate 2	Characteristic Comparison (same/different)
Pulse Width	**IPL-DPC**	10-100 msec	6-100 msec	N/A	Same, within predicate 1 limits
	IR	4-6 sec	2 - 6 sec		Different, no impact on safety or efficacy
	ER:Yag Laser 2940	0.2-2 ms	0.2-2 ms		Same
	Nd:Yag LP Laser	4-30 ms	10, 40, 60, 100 ms		Same, within predicate 1 limits
	Q-Switched Laser	10 ns	20 ns		Different, no impact on safety or efficacy
	RF	Continual	N/A	Continual	Same
Spot size	**IPL-DPC**	1.5, 3.4, 6.4 cm^2	1.5, 3.4, 6.4 cm^2	N/A	Same
	IR	3.4, 6.4 cm^2	1.5, 3.4, 6.4 cm^2		Same. 1.5 cm^2 was removed.
	ER:Yag Laser 2940	7*7 mm 9*9 mm 4 mm	7*7 mm 9*9 mm 1, 2, 4 mm		Same. 1, 2 mm were removed.
	Nd:Yag LP Laser	3, 6 mm	2, 3, 4, 6 mm		Same for 3, 6 mm, 2, 4 mm were removed.
	Q-Switched Laser	2, 4, 6, 12 mm	1, 2, 4, 6 mm		Same for 2, 4, 6 mm, different for 12 mm with no impact on safety or efficacy. 1 mm was removed.
	RF	3.5 (S), 5.5 (L) cm	N/A	3.5, 5.5 cm	Same

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	Proposed Device		Predicate 1	Predicate 2	Characteristic Comparison (same/different)
Repetition rate	**IPL-DPC**	0.4-0.66 Hz	0.4 Hz		Same lower limit, different upper limit, no impact on safety or efficacy.
	IR	N/A	N/A	N/A	N/A
	ER:Yag Laser 2940	1-4 Hz	1-3 Hz		Same lower limit, different upper limit, no impact on safety or efficacy.
	Nd:Yag LP Laser	Up to 1 Hz	Up to 1 Hz		Same
	Q-Switched Laser	1-5 Hz	1-3 Hz		Different, no impact on safety or efficacy
	RF	1Mhz	N/A	1Mhz	Same
Target Treatment Population	Fitzpatrick Skin Types I-VI, most hair color and skin treatment (vascular lesions, pigmented lesions, photorejuvenation and acne). Adult population.		Fitzpatrick Skin Types I-VI, most hair color and skin treatment (vascular lesions, pigmented lesions, photorejuvenation and acne). Adult population.	Adult population.	Same per technology
Materials	Metal, Plastic, Electronic, Laser and optic components and heat exchanger.		Metal, Plastic, Electronic, Laser and optic components and heat exchanger.	Metal, Plastic, Electronic, optic components and heat exchanger.	Same per technology
Coolant Method	Cooling system, treatment gel or air cooling (as required per technology)		Cooling system, treatment gel or air cooling (as required per technology)	Air cooling	Same per technology
Anatomical sites	Skin		Skin	Skin	Same

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Performance Standards

The subsequent assessments were conducted to confirm the validity of the device and the additional modifications made:

- Risk analysis activities in compliance with ISO 14971.
- Electrical safety in accordance with IEC 60601-1 and EMC in accordance with IEC 60601-1-2.
- Laser compatibility testing as required to conform with IEC 60601-2-22 and IEC 60825-1.
- IPL compatibility testing as required to conform with IEC 60601-2-57.
- RF compatibility testing as required to conform with IEC 60601-2-2.

Clinical Performance Data

The Omnimax device Series contains 4 technologies: IPL, IR, Laser and RF.

Regarding IPL, IR and Laser, the Omnimax Series Device Family is the same as the Dermatological Treatment Device Family device family (i.e.: same performance & technological characteristics, same Handpieces, etc.). Therefore, in regard to those technologies, no additional performance or clinical testing is required.

Regarding the RF function of the device series, the safety and efficacy of radiofrequency devices emitting energy with a frequency of 1 MHz and power of 50W is well established in scientific research and clinical studies. Multiple studies with these and similar systems have shown safety in dermatologic therapy and the devices were cleared by the FDA for therapy of wrinkles and rhytids.

Due to the comprehensive studies performed in scientific, research and published in the literature and since the power and frequency of the Omnimax Device Series are within the range of previously cleared values, animal and clinical studies are not required to determine the safety and efficacy of the device.

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Conclusions

Based on the above, the proposed Omnimax Device series is substantially equivalent in terms technology, intended use, performance features and safety and effectiveness to the predicate devices: Dermatological Treatment Device Family (K111303) and the Apollo System (K111026).

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