



June 1, 2023

Candela Corporation  
Danielle Gibboney  
Sr. Regulatory Affairs Specialist  
251 Locke Drive  
Marlborough, Massachusetts 01752

Re: K230990

Trade/Device Name: Candela Vbeam Family of Pulsed Dye Lasers (Vbeam Prima, Vbeam Perfecta)

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

Dated: April 5, 2023

Received: April 6, 2023

Dear Danielle Gibboney:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Jianting Wang -S

Jianting Wang  
Acting 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

## Indications for Use

510(k) Number (if known)

K230990

Device Name

Candela Vbeam Family of Pulsed Dye Lasers (Vbeam Prima, Vbeam Perfecta)

Indications for Use (Describe)

Vbeam Prima is indicated for the following:

595 nm

- General Surgery:
- Photocoagulation of benign cutaneous vascular lesions and benign cutaneous lesions.
- Dermatology/Plastic Surgery:
  - o For treatment of benign cutaneous vascular lesions, such as facial and leg telangiectasia, rosacea, port wine stains, hemangiomas, angioma, spider angioma, Poikiloderma of Civatte, and benign cutaneous lesions, such as warts, scars, striae and Psoriasis and the treatment of wrinkles.
- Treatment of Benign Epidermal Pigmented Lesions.
- Treatment of Inflammatory Acne Vulgaris.
- Gynecology:
  - o Photocoagulation of benign cutaneous lesions and benign vascular lesions in gynecology.
- Podiatry:
  - o Treatment of benign cutaneous lesions, such as warts.
- Pediatric Population
  - o Treatment of cutaneous capillary malformations, also known as port wine stains (PWS), and infantile hemangiomas (IH) / congenital hemangiomas

1064 nm

The Vbeam Prima laser system is intended for the coagulation and hemostasis of benign vascular lesions such as, but not limited to, port wine stains, hemangiomas, warts, telangiectasia, rosacea, Venus lakes, leg veins, spider veins, and poikiloderma of Civatte and treatment of benign cutaneous lesions such as, but not limited to lentigos (age spots), solar lentigos (sun spots), café-au-lait macules, seborrheic keratoses, nevi, chloasma, verrucae, skin tags, and keratoses. The laser is also indicated for the treatment of wrinkles such as, but not limited to, peri-ocular and peri-oral wrinkles.

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.**

## Indications for Use

510(k) Number (if known)

K230990

Device Name

Candela Vbeam Family of Pulsed Dye Lasers (Vbeam Prima, Vbeam Perfecta)

Indications for Use (Describe)

Vbeam Perfecta is indicated for the following:

595 nm

- General Surgery:
- Photocoagulation of benign cutaneous vascular lesions and benign cutaneous lesions.
- Dermatology/Plastic Surgery:
  - o For treatment of benign cutaneous vascular lesions, such as facial and leg telangiectasia, rosacea, port wine stains, hemangiomas, angioma, spider angioma, Poikiloderma of Civatte, and benign cutaneous lesions, such as warts, scars, striae and Psoriasis and the treatment of wrinkles.
- Treatment of Benign Epidermal Pigmented Lesions.
- Treatment of Inflammatory Acne Vulgaris.
- Gynecology:
  - o Photocoagulation of benign cutaneous lesions and benign vascular lesions in gynecology.
- Podiatry:
  - o Treatment of benign cutaneous lesions, such as warts.
- Pediatric Population  
Treatment of cutaneous capillary malformations, also known as port wine stains (PWS), and infantile hemangiomas (IH) / congenital hemangiomas

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.**

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Department of Health and Human Services  
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**510(k) SUMMARY K230990**  
**Candela Vbeam Family of Pulsed Dye Lasers (Vbeam Prima, Vbeam Perfecta)**

This summary of 510(k) submitted in accordance with the requirements of 21 CFR 807.92.

**1. DATE PREPARED**

APRIL 5, 2023

**2. APPLICANT NAME**

Candela Corporation  
251 Locke Drive  
Marlborough MA 01752  
USA

**3. OFFICIAL CORRESPONDENT**

Danielle Gibboney  
Sr. Regulatory Affairs Specialist  
Candela Corporation  
251 Locke Drive  
Marlborough MA 01752 USA  
Phone: 617-904-3820  
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**4. PRODUCT INFORMATION**

**Name of Device:** Candela Vbeam Family of Pulsed Dye Lasers (Vbeam Prima, Vbeam Perfecta)

**Common/Usual Name:** Powered Laser Surgical Instrument

**Classification Name:** Laser surgical instrument for use in general and plastic surgery and in dermatology (per 21 CFR Part 878.4810)

**Device Classification:** Class II (per 21 CFR Part 878.4810)

**Product Code:** GEX

## 5. LEGALLY MARKETED PREDICATE DEVICE FOR CLAIMED EQUIVALENCE:

Predicate Device: Vbeam Prima Laser System (K183452)

Predicate Device: Candela Family of Pulse Laser Systems (K050673)

## 6. DEVICE DESCRIPTION:

The Candela Vbeam Family of Pulsed Dye Lasers includes both the Vbeam Prima and Vbeam Perfecta Laser Systems.

The Vbeam Prima Laser System has been previously cleared for both port wine stains, and hemangiomas under K183452.

The Vbeam Perfecta (Candela Family of Pulse Laser Systems) has been previously cleared for both port wine stains, and hemangiomas under K050673.

This 510(k) Premarket Notification is to expand the indications for use for the Candela Vbeam Family of Pulsed Dye Lasers for the Vbeam Prima Laser System and Vbeam Perfecta to include **the pediatric population for treatment of cutaneous capillary malformations, also known as port wine stains (PWS), and infantile hemangiomas (IH) / congenital hemangiomas** for the 595 nm wavelength. There is no new technology being introduced than what has been previously cleared Vbeam Prima Laser System under its predicate K183452 and Vbeam Perfecta under its predicate K050673.

## 7. INTENDED USE AND INDICATIONS FOR USE:

### Vbeam Prima:

Vbeam Prima is indicated for the following:

#### 595 nm

- General Surgery:
- Photocoagulation of benign cutaneous vascular lesions and benign cutaneous lesions.
- Dermatology/Plastic Surgery:
  - For treatment of benign cutaneous vascular lesions, such as facial and leg telangiectasia, rosacea, port wine stains, hemangiomas, angioma, spider angioma, Poikiloderma of Civatte, and benign cutaneous lesions, such as warts, scars, striae and Psoriasis and the treatment of wrinkles.
- Treatment of Benign Epidermal Pigmented Lesions.
- Treatment of Inflammatory Acne Vulgaris.
- Gynecology:
  - Photocoagulation of benign cutaneous lesions and benign vascular lesions in gynecology.
- Podiatry:
  - Treatment of benign cutaneous lesions, such as warts.
- **Pediatric Population**
  - **Treatment of cutaneous capillary malformations, also known as port wine stains (PWS), and infantile hemangiomas (IH) / congenital hemangiomas**

### 1064 nm

The Vbeam Prima laser system is intended for the coagulation and hemostasis of benign vascular lesions such as, but not limited to, port wine stains, hemangiomas, warts, telangiectasia, rosacea, Venus lakes, leg veins, spider veins, and poikiloderma of Civatte and treatment of benign cutaneous lesions such as, but not limited to lentigos (age spots), solar lentigos (sun spots), café-au-lait macules, seborrheic keratoses, nevi, chloasma, verrucae, skin tags, and keratoses. The laser is also indicated for the treatment of wrinkles such as, but not limited to, peri-ocular and peri-oral wrinkles.

### **Vbeam Perfecta:**

Vbeam Perfecta is indicated for the following:

#### 595 nm

- General Surgery:
- Photocoagulation of benign cutaneous vascular lesions and benign cutaneous lesions.
- Dermatology/Plastic Surgery:
  - For treatment of benign cutaneous vascular lesions, such as facial and leg telangiectasia, rosacea, port wine stains, hemangiomas, angioma, spider angioma, Poikiloderma of Civatte, and benign cutaneous lesions, such as warts, scars, striae and Psoriasis and the treatment of wrinkles.
- Treatment of Benign Epidermal Pigmented Lesions.
- Treatment of Inflammatory Acne Vulgaris.
- Gynecology:
  - Photocoagulation of benign cutaneous lesions and benign vascular lesions in gynecology.
- Podiatry:
  - Treatment of benign cutaneous lesions, such as warts.
- **Pediatric Population**
  - **Treatment of cutaneous capillary malformations, also known as port wine stains (PWS), and infantile hemangiomas (IH) / congenital hemangiomas**

## **8. TECHNOLOGICAL COMPARISON:**

The subject device Candela Vbeam Family of Pulsed Dye Lasers (Vbeam Prima, Vbeam Perfecta) is substantially equivalent and identical in the design, function, and intended use to the Vbeam Prima Laser System under K183452 and Vbeam Perfecta under K050673. The difference between the subject Candela Vbeam Family of Pulsed Dye Lasers (Vbeam Prima, Vbeam Perfecta) and its predicates is the additional indications for **Pediatric Population: Treatment of cutaneous capillary malformations, also known as port wine stains (PWS), and infantile hemangiomas (IH) / congenital hemangiomas** that this Premarket Notification is proposing. The expanded indications between the subject device and its predicates does not raise any new concerns of safety or effectiveness of the device. Thus, based on the information presented in this Premarket Notification, Candela Vbeam Family of Pulsed Dye Lasers (Vbeam Prima, Vbeam Perfecta) is substantially equivalent to its predicates Vbeam Prima Laser System under K183452 and Vbeam Perfecta under K050673. Please refer to specification comparison tables in Table 1 and Table 2 for comparisons between intended use/indications for use, and technological & biological characteristic comparison below.



**Table 1: Intended/Indication for use comparison table.**

<b>Name of Device: 510(k) Product Code Device Class</b>	<b>Candela Vbeam Family of Pulsed Dye Lasers (Vbeam Prima) Proposed Not Assigned GEX Class II</b>	<b>Vbeam Prima Laser System Predicate K183452 GEX Class II</b>	<b>Vbeam Perfecta Laser System Predicate K050673 GEX Class II</b>
<b>Intended use / Indications:</b>	<p>Vbeam Prima is indicated for the following:</p> <p><u>595 nm:</u> General Surgery:</p> <ul style="list-style-type: none"> <li>○ Photocoagulation of benign cutaneous vascular lesions and benign cutaneous lesions.</li> </ul> <p>Dermatology/Plastic Surgery:</p> <ul style="list-style-type: none"> <li>○ For treatment of benign cutaneous vascular lesions, such as facial and leg telangiectasia, rosacea, port wine stains, hemangiomas, angioma, spider angioma, Poikiloderma of Civatte, and benign cutaneous lesions, such as warts, scars, striae and Psoriasis and the treatment of wrinkles.</li> </ul>	<p>Vbeam Prima is indicated for the following:</p> <p><u>595 nm:</u> General Surgery:</p> <ul style="list-style-type: none"> <li>○ Photocoagulation of benign cutaneous vascular lesions and benign cutaneous lesions.</li> </ul> <p>Dermatology/Plastic Surgery:</p> <ul style="list-style-type: none"> <li>○ For treatment of benign cutaneous vascular lesions, such as facial and leg telangiectasia, rosacea, port wine stains, hemangiomas, angioma, spider angioma, Poikiloderma of Civatte, and benign cutaneous lesions, such as warts, scars, striae and Psoriasis and the treatment of wrinkles.</li> </ul>	<p><u>595 nm:</u> General Surgery:</p> <ul style="list-style-type: none"> <li>○ Photocoagulation of benign cutaneous vascular lesions and benign cutaneous lesions.</li> </ul> <p>Dermatology/Plastic Surgery:</p> <ul style="list-style-type: none"> <li>○ For treatment of benign cutaneous vascular lesions, such as facial and leg telangiectasia, rosacea, port wine stains, hemangiomas, angioma, spider angioma, Poikiloderma of Civatte, and benign cutaneous lesions, such as warts, scars, striae and Psoriasis and the treatment of wrinkles.</li> <li>○ Treatment of Benign Epidermal Pigmented Lesions.</li> <li>○ Treatment of Inflammatory Acne Vulgaris.</li> </ul>

<b>Name of Device: 510(k) Product Code Device Class</b>	<b>Candela Vbeam Family of Pulsed Dye Lasers (Vbeam Prima) Proposed Not Assigned <u>GEX</u> Class II</b>	<b>Vbeam Prima Laser System Predicate K183452 <u>GEX</u> Class II</b>	<b>Vbeam Perfecta Laser System Predicate K050673 <u>GEX</u> Class II</b>
	<ul style="list-style-type: none"> <li>○ Treatment of Benign Epidermal Pigmented Lesions.</li> <li>○ Treatment of Inflammatory Acne Vulgaris.</li> </ul> <p>Gynecology:</p> <ul style="list-style-type: none"> <li>○ Photocoagulation of benign cutaneous lesions and benign vascular lesions in gynecology.</li> </ul> <p>Podiatry:</p> <ul style="list-style-type: none"> <li>○ Treatment of benign cutaneous lesions, such as warts.</li> </ul> <p><b>Pediatric Population:</b></p> <ul style="list-style-type: none"> <li>○ <b>Treatment of cutaneous capillary malformations, also known as port wine stains (PWS), and infantile hemangiomas (IH) / congenital hemangiomas</b></li> </ul> <p><u>1064 nm</u> The Vbeam Prima laser system is intended for the coagulation</p>	<ul style="list-style-type: none"> <li>○ Treatment of Benign Epidermal Pigmented Lesions.</li> <li>○ Treatment of Inflammatory Acne Vulgaris.</li> </ul> <p>Gynecology:</p> <ul style="list-style-type: none"> <li>○ Photocoagulation of benign cutaneous lesions and benign vascular lesions in gynecology.</li> </ul> <p>Podiatry:</p> <ul style="list-style-type: none"> <li>○ Treatment of benign cutaneous lesions, such as warts.</li> </ul> <p><u>1064 nm</u> The Vbeam Prima laser system is intended for the coagulation and hemostasis of benign vascular lesions such as, but not limited to, port wine stains, hemangiomas, warts, telangiectasia, rosacea, Venus lakes, leg veins, spider veins, and poikiloderma of Civatte and treatment of benign cutaneous</p>	<p>Gynecology:</p> <ul style="list-style-type: none"> <li>○ Photocoagulation of benign cutaneous lesions and benign vascular lesions in gynecology.</li> </ul> <p>Podiatry:</p> <ul style="list-style-type: none"> <li>○ Treatment of benign cutaneous lesions, such as warts.</li> </ul>

<b>Name of Device: 510(k) Product Code Device Class</b>	<b>Candela Vbeam Family of Pulsed Dye Lasers (Vbeam Prima) Proposed Not Assigned <u>GEX</u> Class II</b>	<b>Vbeam Prima Laser System Predicate <u>K183452</u> <u>GEX</u> Class II</b>	<b>Vbeam Perfecta Laser System Predicate <u>K050673</u> <u>GEX</u> Class II</b>
	<p>and hemostasis of benign vascular lesions such as, but not limited to, port wine stains, hemangiomas, warts, telangiectasia, rosacea, Venus lakes, leg veins, spider veins, and poikiloderma of Civatte and treatment of benign cutaneous lesions such as, but not limited to lentigos (age spots), solar lentigos (sun spots), café-au-lait macules, seborrheic keratoses, nevi, chloasma, verrucae, skin tags, and keratoses. The laser is also indicated for the treatment of wrinkles such as, but not limited to, peri-ocular and peri-oral wrinkles.</p> <p>Vbeam Perfecta is indicated for the following:</p> <p><u>595 nm:</u> General Surgery:</p> <ul style="list-style-type: none"> <li>○ Photocoagulation of benign cutaneous vascular lesions and benign cutaneous</li> </ul>	<p>lesions such as, but not limited to lentigos (age spots), solar lentigos (sun spots), café-au-lait macules, seborrheic keratoses, nevi, chloasma, verrucae, skin tags, and keratoses. The laser is also indicated for the treatment of wrinkles such as, but not limited to, peri-ocular and peri-oral wrinkles.</p>	

<b>Name of Device: 510(k) Product Code Device Class</b>	<b>Candela Vbeam Family of Pulsed Dye Lasers (Vbeam Prima) Proposed Not Assigned <u>GEX</u> Class II</b>	<b>Vbeam Prima Laser System Predicate <u>K183452</u> <u>GEX</u> Class II</b>	<b>Vbeam Perfecta Laser System Predicate <u>K050673</u> <u>GEX</u> Class II</b>
	<p>lesions.</p> <p>Dermatology/Plastic Surgery:</p> <ul style="list-style-type: none"> <li>○ For treatment of benign cutaneous vascular lesions, such as facial and leg telangiectasia, rosacea, port wine stains, hemangiomas, angioma, spider angioma, Poikiloderma of Civatte, and benign cutaneous lesions, such as warts, scars, striae and Psoriasis and the treatment of wrinkles.</li> <li>○ Treatment of Benign Epidermal Pigmented Lesions.</li> <li>○ Treatment of Inflammatory Acne Vulgaris.</li> </ul> <p>Gynecology:</p> <ul style="list-style-type: none"> <li>○ Photocoagulation of benign cutaneous lesions and benign vascular lesions in gynecology.</li> </ul>		

<b>Name of Device: 510(k) Product Code Device Class</b>	<b>Candela Vbeam Family of Pulsed Dye Lasers (Vbeam Prima) Proposed Not Assigned <u>GEX</u> Class II</b>	<b>Vbeam Prima Laser System Predicate <u>K183452</u> <u>GEX</u> Class II</b>	<b>Vbeam Perfecta Laser System Predicate <u>K050673</u> <u>GEX</u> Class II</b>
	Podiatry: <ul style="list-style-type: none"> <li>○ Treatment of benign cutaneous lesions, such as warts.</li> </ul> <b>Pediatric Population: Treatment of cutaneous capillary malformations, also known as port wine stains (PWS), and infantile hemangiomas (IH) / congenital hemangiomas</b>		
<b>Similarities/Differences</b>	Identical to Predicate device, but with expanded indications identified in <b>BOLD</b> .	Identical to the subject device, but without the expanded indications.	Identical to the subject device, but without the expanded indications.

**Table 2: Technological & Biological specification comparison**

General Specifications	Candela Vbeam Family of Pulsed Dye Lasers (Vbeam Prima, Vbeam Perfecta) Proposed <u>Not Assigned</u>		Vbeam Prima Laser System Predicate <u>K183452</u>		Vbeam Perfecta Predicate <u>K050673</u>
Technical Characteristics	Identical		Identical		Identical
Wavelength	595 nm <b>IDENTICAL</b>	1064 nm (Vbeam Prima only) <b>IDENTICAL</b>	595 nm <b>IDENTICAL</b>	1064 nm <b>IDENTICAL</b>	595 nm <b>IDENTICAL</b>
Laser Type	Flash lamp-excited, pulsed dye laser <b>IDENTICAL</b>	Flashlamp-excited, Nd:YAG laser (Vbeam Prima Only) <b>IDENTICAL</b>	Flash lamp-excited, pulsed dye laser <b>IDENTICAL</b>	Flashlamp-excited, Nd:YAG laser <b>IDENTICAL</b>	Flash lamp-excited, pulsed dye laser <b>IDENTICAL</b>
Pulse Energy	Up to 12 J (Vbeam Prima only) <b>IDENTICAL</b>  Up to 8 J (Vbeam Perfecta only) <b>IDENTICAL</b>	Up to 45 J (Vbeam Prima only) <b>IDENTICAL</b>	Up to 12 J <b>IDENTICAL</b>	Up to 45 J <b>IDENTICAL</b>	Up to 8 J <b>IDENTICAL</b>
Pulse Width	0.45-40 ms <b>IDENTICAL</b>	Up to 60 ms (Vbeam Prima Only) <b>IDENTICAL</b>	0.45-40 ms <b>IDENTICAL</b>	Up to 60 ms <b>IDENTICAL</b>	0.45-40 ms <b>IDENTICAL</b>
Laser Pulse Repetition Rate	Up to 1.5 Hz <b>IDENTICAL</b>	Up to 10 Hz ( Vbeam Prima only) <b>IDENTICAL</b>	Up to 1.5 Hz <b>IDENTICAL</b>	Up to 10 Hz <b>IDENTICAL</b>	Up to 1.5 Hz <b>IDENTICAL</b>

General Specifications	Candela Vbeam Family of Pulsed Dye Lasers (Vbeam Prima, Vbeam Perfecta) Proposed <u>Not Assigned</u>	Vbeam Prima Laser System Predicate <u>K183452</u>	Vbeam Perfecta Predicate <u>K050673</u>
Spot Size (mm)	<u>DCD (Vbeam Prima only):</u> 3-15mm HP 3x10mm HP 1.5 Zoom HP <u>CC (Vbeam Prima only):</u> 3-15mm Zoom HP  <b>IDENTICAL</b>  <u>Vbeam Perfecta Only:</u> 3, 5, 7, 10, 12 millimeters and 3x10 (elliptical) <b>IDENTICAL</b>	<u>DCD:</u> 3-15mm HP 3x10mm Zoom HP 1.5 ZHP <u>CC:</u> 3-15mm Zoom HP <b>IDENTICAL</b>	3, 5, 7, 10, 12 millimeters and 3x10 (elliptical) <b>IDENTICAL</b>
Electrical Power	200-240 VAC~; 4600 VA; 50/60 Hz ; single phase (Vbeam Prima only) <b>IDENTICAL</b>  20 - 230 V~ , 50/60 Hz, single phase, 4,000 VA or 17.4 A at 230 V~ (Vbeam Perfecta only)	200-240 VAC~; 4600 VA; 50/60 Hz ; single phase <b>IDENTICAL</b>	220 - 230 V~ , 50/60 Hz, single phase, 4,000 VA or 17.4 A at 230 V~ <b>IDENTICAL</b>
Physical Dimensions /Weight (Console)	280 lbs. (Vbeam Prima only) <b>IDENTICAL</b>  290 lbs. (Vbeam Perfecta only) <b>IDENTICAL</b>	280 lbs. <b>IDENTICAL</b>	290 lbs. <b>IDENTICAL</b>
Patient Contacting Material	Distance Gauges: ULTEM 1000-1000 <b>IDENTICAL</b>	Distance Gauges: ULTEM 1000-1000 <b>IDENTICAL</b>	Distance Gauges: ULTEM 1000-1000 <b>IDENTICAL</b>

## 9. PERFORMANCE DATA:

### Performance Testing: Bench:

The performance testing of the subject Candela Vbeam of Pulsed Dye Lasers (Vbeam Prima, Vbeam Perfecta) is based on the established testing previous cleared under Vbeam Prima Laser System under its predicate K183452 and Vbeam Perfecta under its predicate K050673. There are no changes in the design therefore the subject Candela Vbeam of Pulsed Dye Lasers is based on the established performance testing of the device's predicates.

### Performance Testing-Clinical

A systematic literature search using PubMed, Embase and Cochrane databases, and a supplemental search in Clinicaltrials.gov, was conducted to identify peer-reviewed articles in which the Vbeam PDL System with the 595-nm wavelength was used to treat cutaneous capillary malformations, also known as port wine stains (PWS), and infantile hemangiomas (IH) / congenital hemangiomas in the pediatric population. A total of 33 articles were identified that reported on randomized controlled, prospective, open label, evaluator-blinded clinical trials, or retrospective evaluator-blinded studies that treated at least 10 individuals in each study using the Vbeam 595-nm PDL. The studies were conducted globally in the USA, UK, Europe, and Asia, which included China, Japan, Taiwan, India, and the Middle East. The 33 studies included a total of 7,725 patients of which 5,692 were pediatric (neonates, infants, children, and adolescents) Fitzpatrick Skin Type (FST) I-VI patients treated for hemangioma (4,782 IH, 910 congenital) and 1,354 were pediatric and 679 were pediatric and adult patients (up to 79 years) with Fitzpatrick Skin Type (FST) I- VI treated for PWS / cutaneous capillary malformation.

In conclusion, the data from these published reports support the intended indications for use of the Vbeam 595-nm PDL to treat cutaneous capillary malformations, also known as port wine stains (PWS), and infantile hemangiomas (IH) / congenital hemangiomas in the pediatric population. The articles are identified in Table 3 below.

**Table 3. Identification of Clinical Articles in Candela Vbeam Pulse Dyed Lasers literature search analysis**

<u>No.</u>	<u>Citation</u>	<u>Indication(s):</u>
1	Zhang W, Li F, Yang Y, Xue L, Cao M, Wang L. Hemangioma treatment with pulsed dye laser-distinct parameters used between neonatal and non-neonatal patients. J Cosmet Laser Ther. 2016 Nov;18(7):389-392. doi: 10.1080/14764172.2016.1197402.	Infantile Hemangiomas (pediatric)
2	Yang B, Li L, Zhang LX, Sun YJ, Ma L. Clinical Characteristics and Treatment Options of Infantile Vascular Anomalies. Medicine (Baltimore). 2015 Oct;94(40):e1717. doi:	Vascular Anomalies in children including Infantile Hemangioma & Port Wine Stain



<b>No.</b>	<b>Citation</b>	<b>Indication(s):</b>
	10.1097/MD.0000000000001717.	
3	Sadeghinia A, Moghaddas S, Tavakolpour S, Teimourpour A, Danespazhooch M, Mahmoudi H. Treatment of port wine stains with 595-nm pulsed dye laser in 27 pediatric patients: A prospective study in the Iranian population. J Cosmet Laser Ther. 2019;21(7-8):373-377. doi: 10.1080/14764172.2019.1661489.	Port Wine Stain (pediatric)
4	Yu W, Cen Q, Chen Y, Zhu J, Lin X. Combination Therapy of Pulsed Dye Laser With Intense Pulsed Light in Port-Wine Stain Treatment: A Prospective Side-by-Side Comparison. Dermatol Surg. 2021 Sep 1;47(9):1229-1232. doi: 10.1097/DSS.0000000000003114.	Port Wine Stain (pediatric and adult)
5	Fallahi M, Hallaji Z, Tavakolpour S, Niknam S, Salehi Farid A, Nili A, Teimourpour A, Daneshpazhooch M, Rahmati J, Haddady Abianeh S, Mahmoudi H. Evaluating the efficacy and safety of topical sirolimus 0.2% cream as adjuvant therapy with pulsed dye laser for the treatment of port wine stain: A randomized, double-blind, placebo-controlled trial. J Cosmet Dermatol. 2021 Aug;20(8):2498-2506. doi: 10.1111/jocd.13867.	Port Wine Stain (pediatric and adult)
6	Yu W, Ma G, Qiu Y, Chen H, Jin Y, Yang X, Chang L, Wang T, Hu X, Li W, Lin X. Prospective comparison treatment of 595-nm pulsed-dye lasers for virgin port-wine stain. Br J Dermatol. 2015 Mar; 172(3):684-91. doi: 10.1111/bjd.13356.	Port Wine Stain (pediatric)
7	Bernstein EF. High-energy 595 nm pulsed dye laser improves refractory port-wine stains. Dermatol Surg. 2006 Jan;32(1):26-33. doi: 10.1111/1524-4725.2006.32003.	Port Wine Stain (pediatric and adult)
8	Yu W, Wang T, Zhu J, Qiu Y, Chen H, Jin Y, Yang X, Hu X, Chang L, Chen Y, Ma G, Lin X. EMLA cream does not influence efficacy and pain reduction during pulsed-dye laser treatment of port-wine stain: a prospective side-by-side comparison. Lasers Med Sci. 2018 Apr;33(3):573-579. doi: 10.1007/s10103-017-2415-3.	Port Wine Stain (pediatric and adult)
9	Yu W, Zhu J, Changc SJ, Chen H, Jin Y, Yang X, Wang T, Chang L, Chen Y, Ma G, Lin X. Shorter Treatment Intervals of East Asians with Port-Wine Stain with Pulsed Dye Laser Are Safe and Effective-A Prospective Side-by-Side Comparison. Photomed Laser Surg. 2018 Jan;36(1):37-43. doi: 10.1089/pho.2017.4315.	Port Wine Stain (pediatric and adult)

<b><u>No.</u></b>	<b><u>Citation</u></b>	<b><u>Indication(s):</u></b>
10	Zhu J, Yu W, Wang T, Chen Y, Lyu D, Chang L, Ma G, Lin X. Less is more: similar efficacy in three sessions and seven sessions of pulsed dye laser treatment in infantile port-wine stain patients. <i>Lasers Med Sci.</i> 2018 Nov;33(8):1707-1715. doi: 10.1007/s10103-018-2525-6.	Port Wine Stain (pediatric)
11	Brauer JA, Farhadian JA, Bernstein LJ, Bae YS, Geronemus RG. Pulsed Dye Laser at Subpurpuric Settings for the Treatment of Pulsed Dye Laser-Induced Ecchymoses in Patients With Port-Wine Stains. <i>Dermatol Surg.</i> 2018 Feb;44(2):220-226. doi: 10.1097/DSS.0000000000001255.	Port Wine Stain (pediatric and adult)
12	Yu W, Zhu J, Wang L, Qiu Y, Chen Y, Yang X, Chang L, Ma G, Lin X. Double Pass 595 nm Pulsed Dye Laser Does Not Enhance the Efficacy of Port Wine Stains Compared with Single Pass: A Randomized Comparison with Histological Examination. <i>Photomed Laser Surg.</i> 2018 Jun;36(6):305-312. doi: 10.1089/pho.2017.4392.	Virgin Port Wine Stain (pediatric and adult)
13	Yu W, Ying H, Chen Y, Qiu Y, Chen H, Jin Y, Yang X, Wang T, Ma G, Lin X. In Vivo Investigation of the Safety and Efficacy of Pulsed Dye Laser with Two Spot Sizes in Port-Wine Stain Treatment: A Prospective Side-by-Side Comparison. <i>Photomed Laser Surg.</i> 2017 Sep;35(9):465-471. doi: 10.1089/pho.2016.4186.	Port Wine Stain (pediatric and adult)
14	Faurshou A, Togsverd-Bo K, Zachariae C, Haedersdal M. Pulsed dye laser vs. intense pulsed light for port-wine stains: a randomized side-by-side trial with blinded response evaluation. <i>Br J Dermatol.</i> 2009 Feb;160(2):359-64. doi: 10.1111/j.1365-2133.2008.08993.x.	Port Wine Stain (pediatric and adult)
15	Yung A, Sheehan-Dare R. A comparative study of a 595-nm with a 585-nm pulsed dye laser in refractory port wine stains. <i>Br J Dermatol.</i> 2005 Sep;153(3):601-6. doi: 10.1111/j.1365-2133.2005.06707.x.	Refractory Port Wine Stain (pediatric and adult)
16	Yu W, Ma G, Qiu Y, Chen H, Jin Y, Yang X, Hu X, Wang T, Chang L, Zhou H, Li W, Lin X. Why do port-wine stains (PWS) on the lateral face respond better to pulsed dye laser (PDL) than those located on the central face? <i>J Am Acad Dermatol.</i> 2016 Mar;74(3):527-35. doi: 10.1016/j.jaad.2015.08.026.	Port Wine Stain (pediatric and adult)
17	Li L, Kono T, Groff WF, Chan HH, Kitazawa Y, Nozaki M. Comparison study of a long-pulse pulsed dye laser and a long-pulse pulsed alexandrite laser in the treatment of port	Port Wine Stain (pediatric and adult)

<b><u>No.</u></b>	<b><u>Citation</u></b>	<b><u>Indication(s):</u></b>
	wine stains. J Cosmet Laser Ther. 2008 Mar;10(1):12-5. doi: 10.1080/14764170701817023.	
18	Tomson N, Lim SP, Abdullah A, Lanigan SW. The treatment of port- wine stains with the pulsed-dye laser at 2-week and 6-week intervals: a comparative study. Br J Dermatol. 2006 Apr;154(4):676-9. doi: 10.1111/j.1365-2133.2005.07113.x.	Port Wine Stain (pediatric and adult)
19	Asahina A, Watanabe T, Kishi A, Hattori N, Shirai A, Kagami S, Watanabe R, Le Pavoux A, Maekawa T, Tamaki K, Ohara K. Evaluation of the treatment of port-wine stains with the 595-nm long pulsed dye laser: a large prospective study in adult Japanese patients. J Am Acad Dermatol. 2006 Mar;54(3):487-93. doi: 10.1016/j.jaad.2005.11.1034.	Port Wine Stain (pediatric and adult)
20	Liu S, Yang C, Yang S, Wang Z, Luo D, Zhang X. Topical application of 5-aminolevulinic acid followed by 595-nm pulsed dye laser irradiation for the treatment of recalcitrant port-wine stains: a primary study. J Cosmet Laser Ther. 2012 Aug;14(4):189-92. doi: 10.3109/14764172.2012.699677.	Recalcitrant Port Wine Stain (pediatric and adult)
21	Woo WK, Jasim ZF, Handley JM. Evaluating the efficacy of treatment of resistant port-wine stains with variable-pulse 595-nm pulsed dye and 532-nm Nd:YAG lasers. Dermatol Surg. 2004 Feb;30(2 Pt 1):158-62; discussion 162. doi: 10.1046/j.1076-0512.2003.30055.x.	Port Wine Stain (pediatric and adult)
22	Peters MA, van Drooge AM, Wolkerstorfer A, van Gemert MJ, van der Veen JP, Bos JD, Beek JF. Double pass 595 nm pulsed dye laser at a 6 minute interval for the treatment of port-wine stains is not more effective than single pass. Lasers Surg Med. 2012 Mar;44(3):199-204. doi: 10.1002/lsm.22011.	Port Wine Stain (pediatric and adult)
23	Tremaine AM, Armstrong J, Huang YC, Elkeeb L, Ortiz A, Harris R, Choi B, Kelly KM. Enhanced port-wine stain lightening achieved with combined treatment of selective photothermolysis and imiquimod. J Am Acad Dermatol. 2012 Apr;66(4):634-41. doi: 10.1016/j.jaad.2011.11.958.	Port Wine Stain (pediatric and adult)
24	Frohm Nilsson M, Passian S, Wiegleb Edstrom D. Comparison of two dye lasers in the treatment of port-wine stains. Clin Exp Dermatol. 2010 Mar;35(2):126-30. doi: 10.1111/j.1365-	Port Wine Stain (pediatric and adult)

<b><u>No.</u></b>	<b><u>Citation</u></b>	<b><u>Indication(s):</u></b>
	2230.2009.03399.x.	
25	Thajudheen CP, Jyothy K, Priyadarshini A. Treatment of port-wine stains with flash lamp pumped pulsed dye laser on Indian skin: a six year study. J Cutan Aesthet Surg. 2014 Jan;7(1):32-6. doi: 10.4103/0974-2077.129973.	Port Wine Stain (pediatric and adult)
26	He HY, Shi WK, Jiang JC, Gao Y, Xue XM. An exploration of optimal time and safety of 595-nm pulsed dye laser for the treatment of early superficial infantile hemangioma. Dermatol Ther. 2022 May;35(5):e15406. doi: 10.1111/dth.15406.	Infantile Hemangioma (pediatric)
27	Kono T, Sakurai H, Groff WF, Chan HH, Takeuchi M, Yamaki T, Soejima K, Nozaki M. Comparison study of a traditional pulsed dye laser versus a long-pulsed dye laser in the treatment of early childhood hemangiomas. Lasers Surg Med. 2006 Feb;38(2):112-5. doi: 10.1002/lsm.20257.	Hemangioma (pediatric)
28	Hartmann F, Lockmann A, Grönemeyer LL, Haenssle HA, Zutt M, von Fintel H, Kühnle I, Schön MP, Thoms KM. Nd:YAG and pulsed dye laser therapy in infantile haemangiomas: a retrospective analysis of 271 treated haemangiomas in 149 children. J Eur Acad Dermatol Venereol. 2017 Aug;31(8):1372-1379. doi: 10.1111/jdv.14074.	Infantile Hemangioma (pediatric)
29	Lin MY, Lin CS, Hu S, Chang JM, Chung WH, Zhang ZY, Chang SC, Huo YP. The application of 595-nm pulsed dye laser for vascular anomalies in a Chinese population: a 10-year experience. J Cosmet Laser Ther. 2019;21(3):171-178. doi: 10.1080/14764172.2018.1502450.	Vascular Anomalies including Infantile Hemangioma (pediatric) & Port Wine Stain (pediatric and adult)
30	Rinaldi G, Creissen A, Mahon C, Syed SB. Triple pass laser therapy for recalcitrant facial port wine stains. Lasers Med Sci. 2022 Apr;37(3):1643-1650. doi: 10.1007/s10103-021-03414-x.	Port Wine Stain (pediatric)
31	Li D, Chen B, Zhang H, Yuan Y, Fan W, Ying Z. Retrospective study of the treatment of port-wine stains with 595-nm pulsed dye laser in 261 Chinese patients. Lasers Med Sci. 2020 Oct;35(8):1811-1819. doi: 10.1007/s10103-020-03013-2.	Port Wine Stain (pediatric and adult)
32	Jeon H, Bernstein LJ, Belkin DA, Ghalili S, Geronemus RG. Pulsed Dye Laser Treatment of Port-Wine Stains in Infancy Without the Need for General Anesthesia. JAMA Dermatol. 2019 Apr	Port Wine Stain (pediatric)

<u>No.</u>	<u>Citation</u>	<u>Indication(s):</u>
	1;155(4):435-441. doi: 10.1001/jamadermatol.2018.5249.	
33	Hartmann F, Lockmann A, Himpel O, Kühnle I, Hensen J, Schön MP, Thoms KM. Combination therapy of oral propranolol and combined Nd:YAG/pulsed dye laser therapy in infantile hemangiomas: a retrospective analysis of 48 treated hemangiomas in 30 children. J Dtsch Dermatol Ges. 2020 Sep;18(9):984-993. doi: 10.1111/ddg.14184.	Infantile Hemangioma (pediatric)

## 10. SUBSTANTIAL EQUIVALENCE COMPARISON

When comparing the subject Candela Vbeam of Pulsed Dye Lasers (Vbeam Prima, Vbeam Perfecta) is identical to the previously cleared Vbeam Prima Laser System under K183452 and Vbeam Perfecta under K050673. The additional indications for use do not raise any new issues of safety and effectiveness. There are no technological changes between the subject and predicate devices. The subject Candela Vbeam of Pulsed Dye Lasers (Vbeam Prima, Vbeam Perfecta) is substantially equivalent, in terms of technological characteristics, performance, and intended use to the predicate devices Vbeam Prima Laser System under K183452 and Vbeam Perfecta under K050673 as they are identical.