



April 22, 2026

Ddc Technologies, Inc.  
Joseph Buscarello  
Director of Operations  
311 Woods Ave.  
Oceanside, New York 11572

Re: K253765

Trade/Device Name: Vanish Pro

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: November 25, 2025

Received: November 25, 2025

Dear Joseph Buscarello:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system>.

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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

**Tanisha  
Hithe** Digitally signed by  
Tanisha Hithe  
Date: 2026.04.22  
18:57:45 -04'00'

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

## Indications for Use

510(k) Number (if known)  
K253765

Device Name  
VANISH PRO

### Indications for Use (Describe)

The VANISH PRO is intended for the treatment of benign vascular lesions, benign pigmented lesions, and for tattoo removal and the incision, excision, ablation, vaporization of soft tissue for General dermatology such as, but not limited to treatment of:

1064 nm in QS and PTM Modes:

- Tattoo removal of black, brown, blue, and brown inks
- Removal of benign pigmented lesions
- Treatment of Melasma
- Treatment of Nevus of Ota
- Treatment of Common Nevi, Becker's Nevi
- Treatment of Café au Lait macules (CALMs)
- Skin resurfacing procedures for the treatment of acne scars and wrinkles.

532 nm in QS and PTM Modes:

- Tattoo removal of red, tan, purple, blue, yellow, and orange ink
- Treatment of Café au Lait macules (CALMs)
- Treatment of Lentigines
- Removal of epidermal pigmented lesions
- Removal of minor vascular lesions
- Skin resurfacing procedures for the treatment of acne scars and wrinkles.
- Treatment of seborrheic keratosis
- Treatment of Freckles and Nevi Spilus
- Treatment of post inflammatory hyperpigmentation

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.

**\*DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.\***

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## Contact Details

[21 CFR 807.92\(a\)\(1\)](#)

Applicant Name	DDC Technologies, Inc.
Applicant Address	311 Woods Ave Oceanside NY 11572 United States
Applicant Contact Telephone	516-578-3162
Applicant Contact	Mr. Joseph Buscarello
Applicant Contact Email	buscarello@ddctech.com

## Device Name

[21 CFR 807.92\(a\)\(2\)](#)

Device Trade Name	VANISH PRO
Common Name	VANISH PRO
Classification Name	General & Plastic Surgical Devices
Regulation Number	21 CFR 878.4810
Product Code(s)	GEX

## Legally Marketed Predicate Devices

[21 CFR 807.92\(a\)\(3\)](#)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K213569	HOLLYWOOD SPECTRA Laser System	GEX
K202503	Chrome	GEX

## Device Description Summary

[21 CFR 807.92\(a\)\(4\)](#)

The VANISH PRO is an aesthetic laser system designed and manufactured by DDC Technologies, Inc. The VANISH PRO emits Q-Switched, 1064nm pulses intended for tattoo removal and other indications for use. The VANISH PRO is designed to be pumped and operated by a solid-state Alexandrite laser, primarily the POLYLASE aesthetic laser systems (K040055 and K010715).

## Intended Use/Indications for Use

[21 CFR 807.92\(a\)\(5\)](#)

The VANISH PRO is intended for the treatment of benign vascular lesions, benign pigmented lesions, and for tattoo removal and the incision, excision, ablation, vaporization of soft tissue for General dermatology such as, but not limited to treatment of:

1064 nm in QS and PTM Modes:

- Tattoo removal of black, brown, blue, and brown inks
- Removal of benign pigmented lesions
- Treatment of Melasma
- Treatment of Nevus of Ota
- Treatment of Common Nevi, Becker's Nevi
- Treatment of Café au Lait macules (CALMs)
- Skin resurfacing procedures for the treatment of acne scars and wrinkles.

532 nm in QS and PTM Modes:

- Tattoo removal of red, tan, purple, blue, yellow, and orange ink
- Treatment of Café au Lait macules (CALMs)
- Treatment of Lentigines
- Removal of epidermal pigmented lesions
- Removal of minor vascular lesions
- Skin resurfacing procedures for the treatment of acne scars and wrinkles.
- Treatment of seborrheic keratosis
- Treatment of Freckles and Nevi Spilus
- Treatment of post inflammatory hyperpigmentation

## Indications for Use Comparison

[21 CFR 807.92\(a\)\(5\)](#)

The indications for use of the VANISH PRO are the comparable, and within the range of the two predicate devices listed.

## Technological Comparison

[21 CFR 807.92\(a\)\(6\)](#)

The VANISH PRO operates using the same principles of operation as the listed predicates. They are all solid-state, Q-switched Nd:YAG lasers that emit nanosecond pulses at 1064nm with similar pulse energy, pulse repetition frequency, and modes of operation. All output parameters fall within the range of the predicate devices' parameters.

There are slight differences in the number of pulse trains compared to the predicate. However, the maximum energy delivered to the target area remains within the range of the predicate devices.

Materials, power supplies, and other sub components are comparable to the predicates and many other devices of the same type that have been produced for decades.

## Non-Clinical and/or Clinical Tests Summary & Conclusions

[21 CFR 807.92\(b\)](#)

The output parameters of the subject device were validated via independent bench testing.

Software verification and validation testing consistent with basic documentation were conducted in accordance with the recommendations provided in the FDA guidance document "Content of Premarket Submissions for Device Software Functions".

The VANISH PRO distance gauge in its final finished form is identical to the distance gauge of the predicate device, the "POLYLASE" in formulation, processing, sterilization, and geometry, and no other chemicals have been added (e.g., plasticizers, fillers, additives, cleaning agents, mold release agents). The POLYLASE predicate device was cleared under K040055. Therefore, based on this information, no biocompatibility testing was needed to support substantial equivalence of the VANISH PRO.

The laser system, conduit, and electrical configuration of the device are identical to the Polylase device that was previously cleared under K040055. This submission contains a new handpiece; however, this handpiece does not include electrical components. The EMC, Electrical, Mechanical, and Thermal Safety of the device were previously evaluated in K040055. Therefore, electrical and EMC testing was not needed for this submission.

### Conclusion:

The VANISH PRO is substantially equivalent to the predicate devices k213569 and k202503 and does not raise new questions of safety or effectiveness.