June 24, 2025

Philips Image Guided Therapy Corporation
Sondra Chandler
Senior Regulatory Affairs Specialist
9965 Federal Dr
Colorado Springs, Colorado 80921

Re: K251358
Trade/Device Name: Bridge Plus Occlusion Balloon
Regulation Number: 21 CFR 870.4450
Regulation Name: Vascular clamp
Regulatory Class: Class II
Product Code: MJN
Dated: April 30, 2025
Received: April 30, 2025

Dear Sondra Chandler:

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.

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) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Rohini Retarekar -S

for Carmen Gacchina Johnson, PhD
Assistant Director
DHT2B: Division of Circulatory Support,
Structural, and Vascular Devices
OHT2: Office of Cardiovascular 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K251358

Device Name
Bridge Plus Occlusion Balloon

Indications for Use *(Describe)*
The Bridge Plus Occlusion Balloon catheter is is indicated for temporary vessel occlusion of the Superior Vena Cava (SVC) and Inferior Vena Cava (SVC) in applications including perioperative occlusion and emergency control of hemorrhage.

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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510(k) Summary

Date Prepared: June 24, 2025

510(k) Submitter / Holder: Philips Image Guided Therapy Corporation
9965 Federal Drive
Colorado Springs, CO 80921.3617
Establishment Registration No: 3007284006

Contact: Sondra Chandler
Senior Regulatory Affairs Specialist
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Subject Device

Device Trade Name:	Bridge Plus Occlusion Balloon
Device Common Name:	Catheter, Intravascular Occluding, Temporary
Device Class:	II
Classification Regulation:	21 CFR 870.4450
Regulation Description:	Vascular Clamp
Product Code:	MJN
510(k) Type:	Traditional
Model Number:	590-002

Predicate Device(s)

The Bridge Plus Occlusion Balloon was compared to the following legally marketed predicate devices:

QXMedical Occlusion Balloon (primary predicate)

510(k) Number:	K183679
Manufacturer:	QXMedical
Trade Name:	Occlusion Balloon Catheter
Device Common Name:	Catheter, Intravascular Occluding, Temporary

Bridge Occlusion Balloon

510(k) Number:	K153530
Manufacturer:	Spectranetics (now a part of Philips IGTD)
Trade Name:	Bridge Occlusion Balloon Catheter
Device Common Name:	Catheter, Intravascular Occluding, Temporary

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Device Description
The Bridge Plus Occlusion Balloon is designed to be delivered percutaneously to the superior vena cava (SVC) or the inferior vena cava (IVC) for the purpose of providing occlusion, emergency control of hemorrhage and perioperative occlusion in the event of an SVC or IVC tear or perforation during a vascular procedure.

The Bridge Plus Occlusion Balloon catheter is constructed of a compliant polyurethane balloon mounted on a 12Fr dual lumen nylon shaft. This guidewire lumen is used to pass the catheter over a guidewire. The balloon has a length of 80mm and inflation diameter ranging from 20-29mm. Three platinum-iridium radiopaque markers are placed within the balloon segment of the catheter to provide visual reference points for balloon positioning within the SVC or IVC prior to inflation.

Intended and Indications for Use
The Bridge Plus Occlusion Balloon Catheter is indicated for temporary vessel occlusion of the Superior Vena Cava (SVC) and Inferior Vena Cava (SVC) in applications including perioperative occlusion and emergency control of hemorrhage.

Technological Characteristics
The Bridge Plus Occlusion Balloon is similar in design characteristics and performance to the predicate devices. Similar to these predicates, the Bridge Plus Occlusion Balloon is deliverable to the target vasculature and is appropriately sized to perform vascular occlusion procedures. The subject device includes vessel specificity (SVC and IVC) in its proposed indication, which differs from the predicates. Materials of construction and balloon and catheter design differ from the predicates. Performance testing data have demonstrated that the Bridge Plus Occlusion Balloon meets performance specifications to support substantial equivalence to the predicate devices.

Performance Data
The following testing was conducted to validate and verify that the subject device met all specifications and was substantially equivalent to the predicate devices:

Design Verification and Validation Testing

- Dimensional and Visual Tests
    - Crossing Profile, Balloon Compliance, Balloon Working Length, Catheter Effective Length, Surface Appearance, Distal Tip Configuration, Luer Compatibility, Guidewire Compatibility
- Performance Testing
    - Deployment and Retraction, Withdrawal Force, Inflation and Deflation Time, Inflated Balloon Size Stability, Balloon Bond Strength, Tip Bond Strength, Hub Bond Strength, Flexibility and Kink, Torque Strength, Vessel Occlusion, Leak Testing, Balloon Fragmentation & Burst Volume, Device Fatigue

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Sterilization
A sterilization adoption assessment was conducted in accordance with ISO 11135:2014 Amd 1 with the following tests:

- Bioburden resistance study to confirm the appropriateness of the existing process challenge devices (PCDs) utilized to validate sterilization cycle (SPNC20123FullCycle) to sterilize the Bridge Plus Occlusion Balloon catheter
- Bioburden method validation including enumeration evaluation

Biocompatibility

- Cytotoxicity
- Sensitization
- Irritation or Intracutaneous Reactivity
- Material Mediated Pyrogenicity
- Acute Systemic Toxicity
- Direct and Extract Hemolysis
- Partial Thromboplastin Time
- Platelet & Leukocyte Count
- Comparative Surface Analysis
- Complement Activation

Preclinical and Clinical Data
No new preclinical or clinical data were required to demonstrate substantial equivalence of the Bridge Plus Occlusion Balloon to the predicate devices.

Substantial Equivalence
Based on the similarities in design between the subject and predicate devices, and the performance data, the Bridge Plus Occlusion Balloon is substantially equivalent to both the legally marketed QX Medical Occlusion Balloon Catheter and Bridge Occlusion Balloon Catheter.