



March 18, 2025

Teleflex Medical  
Jane Doll  
Regulatory Affairs Team Lead  
3015 Carrington Mill Blvd  
Morrisville, North Carolina 27560

Re: K243553

Trade/Device Name: QuikClot Control+ Hemostatic Device  
Regulation Number: 21 CFR 878.4454  
Regulation Name: Non-Absorbable, Hemostatic Gauze For Temporary Internal Use  
Regulatory Class: Class II  
Product Code: POD, QSY  
Dated: February 14, 2025  
Received: February 14, 2025

Dear Jane Doll:

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/combo-products/guidance-regulatory-information/postmarketing-safety-reporting-combo-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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

**TEK N. LAMICHHANE -S**

Tek Lamichhane, Ph.D.  
Assistant Director  
DHT4B: Division of Plastic and  
Reconstructive Surgery Devices  
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Infection Control Devices  
Office of Product Evaluation and Quality  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)  
K243553

Device Name  
QuikClot Control+ Hemostatic Device

Indications for Use (Describe)

QuikClot Control+ is indicated for temporary control of external and identifiable sites of internal mild, moderate, severe, and life-threatening bleeding.

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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**510(k) SUMMARY  
(K243553)****I. Submitter Information**

Name: Teleflex Medical  
Address: 3015 Carrington Mill Blvd  
Morrisville, NC 27560

Contact Person: Jane Doll  
Telephone Number: (919) 361-3973  
Email: [jane.doll@teleflex.com](mailto:jane.doll@teleflex.com)

Date Prepared: February 21, 2025

**II. Device Name**

Name of Device: QuikClot Control+™ Hemostatic Device  
Common Name: Temporary, Internal Use Hemostatic Wound Dressing  
Classification Name: Temporary, Internal Use Hemostatic (21 CFR 878.4454)  
Regulatory Class: II  
Product Code: POD

**III. Predicate Device**

Primary Predicate: QuikClot Control+™ Hemostatic Dressing (K220971)  
Secondary Predicate: D2 Hemostatic Dressing (K140757)

**IV. Device Description and Mechanism of Action****Device Description**

QuikClot Control+™ Hemostatic Device consists of a white to off-white to yellow, sterile, X-Ray detectable hemostatic dressing and is packaged for aseptic removal.

**Mechanism of Action**

The QuikClot Control+ Hemostatic Devices are packed into or on the wound and pressure is applied. Pressure is maintained until the bleeding is controlled and may be left in place up to 48 hours. More than one QuikClot Control+ hemostatic device can be used. Hemostasis is achieved through the activity of the hemostatic agent kaolin bound to the gauze in conjunction with compression.

**V. Indications for Use**

QuikClot Control+ is indicated for temporary control of external and identifiable sites of internal mild, moderate, severe, and life-threatening bleeding.

**VI. Technological Characteristics and Substantial Equivalence**

The Proposed Device is identical to the Primary Predicate in terms of intended use, target population, materials of construction (including hemostatic agent and binder), sizes, prescription use, patient contact time, how supplied, sterilization method, shelf-life, single use, packaging and biocompatibility. Additionally, the Proposed Device is identical in

formulation, mode of operation/mechanism of action, and scientific technological characteristics.

The change to the device is a modification to the indications for use. **Table 1** below provides a comparison of the Proposed Device and Primary Predicate Device.

**Table 1. Substantial Equivalence Comparison to Primary Predicate**

Parameter	Proposed Device (K243553) QuikClot Control+™ Hemostatic Device	Primary Predicate Device – K220971 QuikClot Control+™ Hemostatic Dressing	Comparison
<b>Indications for Use</b>	QuikClot Control+ is indicated for temporary control of external and identifiable sites of internal mild, moderate, severe, and life-threatening bleeding.	<p>QuikClot Control+ Hemostatic Dressing is indicated for temporary control of internal organ space bleeding for patients displaying class III or class IV bleeding. It may also be used for control of severely bleeding wounds such as surgical wounds and traumatic injuries.</p> <p>Cardiac surgical procedures: for temporary control of mild and moderate bleeding in cardiac surgical procedures, as well as in patients displaying Class III or class IV bleeding.</p> <p>Bone surfaces following sternotomy: to control bleeding from bone surfaces following a sternotomy.</p>	Modification to the indications for use wording to align with the wording of the VIBe scale for mild, moderate, severe, and life-threatening, covering the full range of identifiable sites of internal bleeding.
<b>Intended Use</b>	<p>To control internal and external bleeding.</p> <p>To control bone surface bleeding.</p>	<p>To control internal and external bleeding.</p> <p>To control bone surface bleeding at the sternotomy access site.</p>	<p>Minor edits for clarity.</p> <p>Removal of “at the sternotomy access site” to support the</p>

Parameter	Proposed Device (K243553) QuikClot Control+™ Hemostatic Device	Primary Predicate Device – K220971 QuikClot Control+™ Hemostatic Dressing	Comparison
	<p>To control suture line bleeding following cardiac surgical procedures, such as but not limited to, heart valve repairs or replacements, coronary artery bypass graft surgery (CABG), or aortic aneurysm repairs.</p> <p>To control bleeding due to tears, lacerations, and abrasions to include epicardial repairs with or without sutures.</p> <p>May be used with or without the use of cardiopulmonary bypass systems. The dressing can be applied to control bleeding while the patient is ‘on or off pump’.</p> <p>May be used with or without autotransfusion (blood salvage) equipment.</p> <p>May be used on patients on anticoagulation / antiplatelet medication.</p>	<p>To control suture line bleeding following cardiac surgical procedures, such as but not limited to, heart valve repairs or replacements, coronary artery bypass graft surgery (CABG), or aortic aneurysm repairs.</p> <p>To control bleeding due to tears, lacerations, and abrasions to include epicardial repairs with or without sutures.</p> <p>To be used with or without the use of cardiopulmonary bypass systems. The dressing can be applied to control bleeding while the patient is ‘on or off pump’.</p> <p>To be used with or without autotransfusion (blood salvage) equipment.</p> <p>To be used on patients on anticoagulation / antiplatelet medication.</p>	proposed indications for use.
<b>Target Population</b>	All patient populations needing control of bleeding.	All patient populations needing control of bleeding.	Same
<b>Contraindication</b>	Do not leave QuikClot Control+ in place for more than 48 hours.	Do not leave QuikClot Control+ in place for more than 48 hours.	Same

Parameter	Proposed Device (K243553) QuikClot Control+™ Hemostatic Device	Primary Predicate Device – K220971 QuikClot Control+™ Hemostatic Dressing	Comparison
	QuikClot Control+ is not indicated for intraluminal vascular use.	QuikClot Control+ is not indicated for intraluminal vascular use.	
<b>Warnings</b>	<ul style="list-style-type: none"> <li>• QuikClot Control+™ is not to be blindly inserted into a non-compressible internal wound.</li> <li>• Adhesion formation associated with QuikClot Control+ Dressing use was noted in preclinical studies; adhesions were also observed with control materials. It is not known whether adhesions elicited by QuikClot Control+ Dressing are equivalent to those caused by control materials.</li> <li>• QuikClot Control+ Dressing is not absorbable and must be removed from the wound prior to wound closure.</li> <li>• Read all package insert warnings, precautions, and instructions prior to use. Failure to do so may result in severe patient injury or death.</li> </ul>	<ul style="list-style-type: none"> <li>• Adhesion formation associated with QuikClot Control+ Dressing use was noted in preclinical studies; adhesions were also observed with control materials. It is not known whether adhesions elicited by QuikClot Control+ Dressing are equivalent to those caused by control materials.</li> <li>• QuikClot Control+ Dressing is not absorbable and must be removed from the wound prior to wound closure.</li> <li>• Warning: Read all package insert warnings, precautions, and instructions prior to use. Failure to do so may result in severe patient injury or death.</li> <li>• Warning: Single use: Do not reuse, reprocess or re-sterilize. Reuse of device creates a</li> </ul>	Addition of “QuikClot Control+™ is not to be blindly inserted into a non-compressible internal wound.”

Parameter	Proposed Device (K243553) QuikClot Control+™ Hemostatic Device	Primary Predicate Device – K220971 QuikClot Control+™ Hemostatic Dressing	Comparison
	<ul style="list-style-type: none"> <li>Single use: Do not reuse, reprocess or re-sterilize. Reuse of device creates a potential risk of serious injury and/or infection which may lead to death. Reprocessing of medical devices intended for single use only may result in degraded performance or a loss of functionality.</li> </ul>	<p>potential risk of serious injury and/or infection which may lead to death. Reprocessing of medical devices intended for single use only may result in degraded performance or a loss of functionality.</p>	
<b>Materials of Construction</b>	Gauze Substrate, Kaolin (hemostatic agent), and Calcium Alginate (binder)	Gauze Substrate, Kaolin (hemostatic agent), and Calcium Alginate (binder)	Same
<b>Sizes</b>	Various sizes including but not limited to 1" x 1", 3 ply; 4" x 2", 6 ply or 10 ply; 4" x 6", 6 ply or 10 ply; 4" x 8", 6 -10 plies; 4" x 12", 9 ply 5" x 5", 4 ply 8" x 8", 2 ply 12" x 12", 3 ply 3" x 4 yards, 1 ply 3" x 2 yards, 1 ply	Various sizes including but not limited to 1" x 1", 3 ply; 4" x 2", 6 ply or 10 ply; 4" x 6", 6 ply or 10 ply; 4" x 8", 6 -10 plies; 4" x 12", 9 ply 5" x 5", 4 ply 8" x 8", 2 ply 12" x 12", 3 ply 3" x 4 yards, 1 ply 3" x 2 yards, 1 ply	Same
<b>Prescription Use or Over-the-Counter (OTC)</b>	Prescription Use	Prescription Use	Same
<b>Patient Contact Time</b>	Up to 48 hours	Up to 48 hours	Same
<b>How Supplied</b>	Sterile	Sterile	Same
<b>Sterilization Method</b>	Gamma	Gamma	Same
<b>Shelf-life</b>	39 months	39 months	Same

Parameter	Proposed Device (K243553) QuikClot Control+™ Hemostatic Device	Primary Predicate Device – K220971 QuikClot Control+™ Hemostatic Dressing	Comparison
<b>Single Use / Reusable</b>	Single use	Single use	Same
<b>Packaging</b>	Peelable foil pouch	Peelable foil pouch	Same
<b>Biocompatibility</b>	Biocompatible materials used (per ISO 10993-1 prolonged contact duration).	Biocompatible materials used (per ISO 10993-1 prolonged contact duration).	Same

The Proposed Device is substantially equivalent to the Secondary Predicate Device in that both devices are indicated for temporary control of severe bleeding and both are intended to control external bleeding. Moreover, the Proposed Device and the Secondary Predicate Device contain identical materials of construction (including hemostatic agent and binder). Accordingly, the Proposed Device and Secondary Predicate Device have identical mechanisms of action. The Proposed Device is also identical to the Secondary Predicate in terms of prescription use, how supplied, sterilization method, single use, packaging and biocompatibility. For differences in sizes, patient contact time, and shelf life, the Proposed Device is supported by testing and data from the Primary Predicate for the differences in size, and the longer patient contact time and shelf-life.

**Table 2** below provides a comparison of the proposed device and secondary predicate device.

**Table 2. Substantial Equivalence Comparison to Secondary Predicate**

Parameter	Proposed Device(K243553) QuikClot Control+™ Hemostatic Device	Secondary Predicate Device – K140757 D2 Hemostatic Dressing	Comparison
<b>Indications for Use</b>	QuikClot Control+ is indicated for temporary control of external and identifiable sites of internal mild, moderate, severe, and life-threatening bleeding.	D2 Hemostatic Dressing is intended for use as a hemostatic dressing for the temporary control of severely bleeding wounds such as surgical wounds and traumatic injuries.	Both are indicated for temporary, external control of severe bleeding.
<b>Intended Use</b>	To control internal and external bleeding.  To control bone surface bleeding.	To control external bleeding.	Both are intended to control external bleeding.

Parameter	Proposed Device(K243553) QuikClot Control+™ Hemostatic Device	Secondary Predicate Device – K140757 D2 Hemostatic Dressing	Comparison
	<p>To control suture line bleeding following cardiac surgical procedures, such as but not limited to, heart valve repairs or replacements, coronary artery bypass graft surgery (CABG), or aortic aneurysm repairs.</p> <p>To control bleeding due to tears, lacerations, and abrasions to include epicardial repairs with or without sutures.</p> <p>May be used with or without the use of cardiopulmonary bypass systems. The dressing can be applied to control bleeding while the patient is ‘on or off pump’.</p> <p>May be used with or without autotransfusion (blood salvage) equipment.</p> <p>May be used on patients on anticoagulation / antiplatelet medication.</p>		
<b>Target Population</b>	All patient populations needing control of bleeding.	Battleground / Pre-Hospital / Hospital / Medical Office	The Target Population is broader and defined in line with the Primary Predicate.
<b>Contraindication</b>	Do not leave QuikClot Control+ in place for more than 48 hours.	[No Contraindications stated.]	The warnings are in line with the Primary Predicate device.

Parameter	Proposed Device(K243553) QuikClot Control+™ Hemostatic Device	Secondary Predicate Device – K140757 D2 Hemostatic Dressing	Comparison
	<p>QuikClot Control+ is not indicated for intraluminal vascular use.</p>		<p>Vascular use appears as a Contraindication in the Proposed Device but appears as a Warning in the Secondary Predicate Device (see Warnings, 5<sup>th</sup> bullet point).</p>
<p><b>Warnings</b></p>	<ul style="list-style-type: none"> <li>• QuikClot Control+™ is not to be blindly inserted into a non-compressible internal wound.</li> <li>• Adhesion formation associated with QuikClot Control+ Dressing use was noted in preclinical studies; adhesions were also observed with control materials. It is not known whether adhesions elicited by QuikClot Control+ Dressing are equivalent to those caused by control materials.</li> <li>• QuikClot Control+ Dressing is not absorbable and must be removed from the wound prior to wound closure.</li> <li>• Read all package insert warnings, precautions, and</li> </ul>	<ul style="list-style-type: none"> <li>• Product is not absorbable and must be removed from the wound prior to wound closure.</li> <li>• The D2 Hemostatic Dressing is not intended as a substitute for meticulous surgical technique, the use of sterile procedures, and the proper application of ligatures or other conventional procedures to control bleeding.</li> <li>• The D2 Hemostatic Dressing must not remain in the wound for longer than 24 hours.</li> <li>• Avoid contact with eyes.</li> <li>• The safety and effectiveness of the D2 Hemostatic Dressing for use in</li> </ul>	<p>The Warnings are in line with the Primary Predicate.</p> <p>Addition of “QuikClot Control+™ is not to be blindly inserted into a non-compressible internal wound.”</p>

Parameter	Proposed Device(K243553) QuikClot Control+™ Hemostatic Device	Secondary Predicate Device – K140757 D2 Hemostatic Dressing	Comparison
	<p>instructions prior to use. Failure to do so may result in severe patient injury or death.</p> <p>Single use: Do not reuse, reprocess or re-sterilize. Reuse of device creates a potential risk of serious injury and/or infection which may lead to death. Reprocessing of medical devices intended for single use only may result in degraded performance or a loss of functionality.</p>	<p>neurological, ophthalmic, spinal, GI, orthopedic (bone repair), all anastomoses (including vascular) and femoral artery puncture sites have not been established.</p>	
<b>Materials of Construction</b>	Gauze Substrate, Kaolin (hemostatic agent), and Calcium Alginate (binder)	Gauze Substrate, Kaolin (hemostatic agent), and Calcium Alginate (binder)	Same
<b>Sizes</b>	<p>Various sizes including but not limited to</p> <p>1" x 1", 3 ply;  4" x 2", 6 ply or 10 ply;  4" x 6", 6 ply or 10 ply;  4" x 8", 6 -10 plies;  4" x 12", 9 ply  5" x 5", 4 ply  8" x 8", 2 ply  12" x 12", 3 ply  3" x 4 yards, 1 ply  3" x 2 yards, 1 ply</p>	<p>Various sizes ranging from 1" x 1" x 1 ply to 4" x 12ft x 2 ply</p>	<p>The Proposed Device includes additional sizes as cleared in the Primary Predicate, K220971.</p>
<b>Prescription Use or Over-the-Counter (OTC)</b>	Prescription Use	Prescription Use	Same
<b>Patient Contact Time</b>	Up to 48 hours	Up to 24 hours	The Proposed Device can be used

Parameter	Proposed Device(K243553) QuikClot Control+™ Hemostatic Device	Secondary Predicate Device – K140757 D2 Hemostatic Dressing	Comparison
			for 24 hours, up to 48 hours. This is in line with the Primary Predicate.
<b>How Supplied</b>	Sterile	Sterile	Same
<b>Sterilization Method</b>	Gamma	Gamma	Same
<b>Shelf-life</b>	39 months	27 months	The Proposed Device aligns with the longer shelf-life of the Primary Predicate.
<b>Single Use / Reusable</b>	Single-use	Single-use	Same
<b>Packaging</b>	Peelable foil pouch	Peelable foil pouch	Same
<b>Biocompatibility</b>	Biocompatible materials used (per ISO 10993-1 prolonged contact duration).	Biocompatible materials used (per ISO 10993-1 prolonged contact duration).	Same

## VII. Performance Data

The Proposed Device is identical to the Primary Predicate Device in reprocessing, sterility (including sterilization method, pyrogenicity, and packaging), and shelf-life. The Proposed Device will continue to be sterilized using the existing validated parameters and commercialized utilizing the same packaging system as the Primary Predicate. All previously executed performance testing (animal, biocompatibility, bench, stability) remain applicable. No new testing was necessary.

## VIII. Clinical Study

Real-world data (RWD) was collected through a retrospective observational study of the medical records of patients treated with QuikClot Control+™. This study was a retrospective, statistically powered, observational study of emergency, trauma, and surgical patients on whom QuikClot Control+ was used to control internal or external bleeding.

Participants of the retrospective observational study were healthcare professionals from 74 individual sites covering 27 states in the United States that were qualified to use the device and who performed the clinical procedures in which the device was used. The sample size was statistically calculated and powered on the primary endpoint ‘successful control of bleeding’. The primary endpoint assessed performance of the device while safety was

assessed as secondary endpoints based on device-specific adverse events experienced with QuikClot Control+ use.

RWD was collected on both internal and external use of the device to control all grades of bleeding (mild, moderate, severe, life-threatening) in multiple and varied anatomical sites in a total of 603 patient cases. A total of 404 internal uses and 199 external uses were captured. Based on the primary endpoint, QuikClot Control+ successfully controlled bleeding in 98.7% of internal use cases and in 97% of external use cases, achieving the primary endpoints. QuikClot Control+ achieved all safety objectives with rates of hematoma at 0.5% in internal use cases and at 1% in external use cases. There were no reports of thrombus formation or thromboembolisation with either internal or external use.

In conclusion, results show successful control of both internal and external bleeding in all grades of bleeding, including mild, moderate, severe, and life-threatening. As evidenced from the Real-World Data of 603 patients, QuikClot Control+ has been used successfully across many surgery types and specialties to treat patients with bleeding in all anatomical sites in a broad and generalizable patient population. The study provides sufficient clinical evidence of the effectiveness and safety of QuikClot Control+ to modify the indications for use as described in **Table 1** above.

#### **IX. Conclusions**

The Proposed Device is identical to the Primary Predicate in terms of intended use, target population, materials of construction (including hemostatic agent and binder), sizes, prescription use, patient contact time, how supplied, sterilization method, shelf-life, single use, packaging and biocompatibility. Additionally, the Proposed Device is identical in formulation, mode of operation/mechanism of action, and scientific technological characteristics. The Proposed Device is substantially equivalent to the Secondary Predicate. Design modifications or manufacturing process changes were not required to support the modification to the indications for use. All previously executed performance testing (animal, biocompatibility, bench, stability) remain applicable. The clinical testing Real-World Data collection demonstrated that QuikClot Control+™ Hemostatic Device is safe and effective for temporary control of external and identifiable sites of internal mild, moderate, severe, and life-threatening bleeding.