December 16, 2022

Becton, Dickinson and Company
Alexandra Kirby
Staff Regulatory Affairs Specialist
1 Becton Drive
Franklin Lakes, New Jersey 07417

Re: K223243
Trade/Device Name: BD Microtainer® Contact-Activated Lancets; BD Microtainer® Quikheel™ Lancets
Regulation Number: 21 CFR 878.4850
Regulation Name: Blood Lancets
Regulatory Class: Class II
Product Code: FMK
Dated: October 19, 2022
Received: October 20, 2022

Dear Alexandra Kirby:

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

Sincerely,

Jessica Carr -S

for Long Chen, Ph.D.
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)*
K223243

Device Name
BD Microtainer® Contact-Activated Lancets and BD Microtainer® Quikheel™ Lancets

Indications for Use *(Describe)*

BD Microtainer® Contact-Activated Lancets
The BD Microtainer® Contact-Activated Lancet is a sterile, single-use, permanently retracting, lancing device used to perform fingerstick punctures in in adults, adolescents, children, and infants (greater than 6 months of age and 10 kg [22 lbs]). The device is intended to be used by a healthcare professional in a clinical setting to obtain capillary blood specimens for testing utilizing small amounts of blood.

BD Microtainer® Quikheel™ Lancets
The BD Microtainer® Quikheel™ Lancet is a sterile, single-use medical device with a push-button activated, permanently retracting blade. The device is intended to be used by healthcare professionals to perform heel sticks in neonates, pre-term (preemie) and full-term infants (non-walking) to obtain capillary blood specimens for testing utilizing small amounts of blood.

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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5 510(K) SUMMARY

BD Microtainer® Contact-Activated Lancets and BD Microtainer® Quikheel™ Lancets

Summary Preparation Date: December 16, 2022

Submitted by:
Becton, Dickinson and Company
1 Becton Drive
Franklin Lakes, NJ 07417-1885
Phone: (201) 847-6800

Contact:
Alexandra Kirby
Staff Regulatory Affairs Specialist
Email: Alexandra.Kirby@bd.com
Phone: (862) 774-2318

Proprietary Names: BD Microtainer® Contact-Activated Lancets, BD Microtainer® Quikheel™ Lancets

Common or Usual Names: Single Use Only Blood Lancet With An Integral Sharps Injury Prevention Feature

Regulatory Information
Classification Name: Blood Lancets
Classification Regulation: 21 CFR 878.4850(a)
Regulatory Class: Class II
Product Code: FMK
Classification Panel: General & Plastic Surgery

Predicate Device: BD Microtainer® Contact-Activated Lancets, BD Microtainer® Quikheel™ Lancets (previously Class I exempt, reclassified to Class II devices requiring a 510(k) under Docket No. FDA-2016-N-0040 on November 22, 2021)

Device Establishment: Becton, Dickinson and Company

Registration Number: 2243072

Performance Standards:

1. EN ISO 13485:2016 Medical devices – Quality management systems – Requirements for regulatory purposes

2. EN ISO 14971:2019 Medical Devices – Application of risk management to medical devices

3. EN ISO 23908:2013 Sharps injury protection - Requirements and test methods - Sharps protection features for single-use hypodermic needles, introducers for catheters and needles used for blood sampling

4. ISO 11607-1:2019 Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems*

5. ISO 11607-2:2019 Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes*

6. EN ISO 15223-1:2021 Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements

7. EN ISO 20417:2021 Medical devices - Information to be supplied by the manufacturer

8. EN 556-1:2001/AC:2006 Sterilization Of Medical Devices - Requirements For Medical Devices To Be Designated "Sterile" - Part 1: Requirements For Terminally Sterilized Medical Devices

9. EN ISO 11137-1:2015/A2:2019 Sterilization of health care products - Radiation Part 1: Requirements for development, validation, and routine control of a sterilization process for medical devices

10. EN ISO 11137-2:2015 Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose

11. EN ISO 11137-3:2017 Sterilization of health care products — Radiation — Part 3: Guidance on dosimetric aspects of development, validation and routine control

12. EN ISO 11737-1:2018/A1:2021 Sterilization of health care products - Microbiological methods - Part 1: Determination of a population of microorganisms on products

13. EN ISO 11737-2:2020 Sterilization of medical devices - Microbiological methods – Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process

14. ISO/TS 13004:2013 Sterilization of health care products — Radiation — Substantiation of selected sterilization dose: Method VD_{max}^{SD}

15. ISO 10993-1:2018 Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process

16. EN ISO 10993-2:2006 Biological evaluation of medical devices – Part 2: Animal welfare requirements

17. ISO 10993-4:2017 Biological evaluation of medical devices – Part 4: Selection of tests for interactions with blood

18. ISO 10993-5:2009 Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity

19. ISO 10993-10:2010 Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization

20. ISO 10993-11:2017 Biological evaluation of medical devices – Part 11: Tests for systemic toxicity

21. ISO 10993-12:2012 Biological evaluation of medical devices – Part 12: Sample preparation and reference materials

22. ISO 10993-17:2002 Biological evaluation of medical devices – Part 17: Establishment of allowable limits for leachable substances

23. ISO 10993-18:2020 Biological evaluation of medical devices – Part 18: Chemical characterization of materials

24. ISO 10993-23:2021, Biological Evaluation of Medical Devices – Part 23: Tests for irritation.

25. ASTM F1980-16 Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices

26. ASTM D4169-16 Standard Practice for Performance Testing of Shipping Containers and Systems

27. ASTM F2096-11 Standard Test Method for Detecting Gross Leaks in Packaging by Internal Pressurization (Bubble Test)

28. ASTM F88 Standard Test Method for Seal Strength of Flexible Barrier Materials

29. EN ISO 22442-1:2020 Medical devices utilizing animal tissues and their derivatives - Part 1: Application of risk management

30. EN ISO 22442-2:2020 Medical devices utilizing animal tissues and their derivatives - Part 2: Controls on sourcing, collection and handling

31. EN ISO 22442-3:2007 Medical devices utilizing animal tissues and their derivatives - Part 3: Validation of the elimination and/or inactivation of viruses and transmissible spongiform encephalopathy (TSE) agents

32. CLSI GP42-A7: Collection of Capillary Blood Specimens, 7th Edition

For the BD Microtainer® Contact-Activated Lancets, only partial compliance is claimed for standards marked with an asterisk (*).

Indications for Use

BD Microtainer® Contact-Activated Lancets

The BD Microtainer® Contact-Activated Lancet is a sterile, single-use, permanently retracting, lancing device used to perform fingerstick punctures in adults, adolescents, children, and infants (greater than 6 months of age and 10 kg [22 lbs]). The device is intended to be used by a healthcare professional in a clinical setting to obtain capillary blood specimens for testing utilizing small amounts of blood.

BD Microtainer® Quikheel™ Lancets

The BD Microtainer® Quikheel™ Lancet is a sterile, single-use medical device with a push-button activated, permanently retracting blade. The device is intended to be used by healthcare professionals to perform heel sticks in neonates, pre-term (preemie) and full-term infants (non-walking) to obtain capillary blood specimens for testing utilizing small amounts of blood.

Device Description

BD Microtainer® Contact-Activated Lancets

The BD Microtainer® Contact-Activated Lancets are sterile, single-use lancets with a permanently retracting stainless steel needle or blade used for the purpose of obtaining capillary blood specimens for testing utilizing small amounts of blood. The BD Microtainer® Contact-Activated Lancet needle/blade is never visible and remains sterile until the protective tab cap is removed. The BD Microtainer® Contact-Activated Lancet is activated by applying pressure against the puncture site upon contact; after skin puncture, the needle/blade returns into the device. Once activated, the device is auto-disabled and cannot be re-used (when used as intended) to minimize the chance of an accidental fingerstick and contamination.

The BD Microtainer® Contact-Activated Lancets are made up of the following key functional components:

1. Rear Cap
2. Drive Spring
3. Lever Element
4. Needle Carrier with Protective Tab
5. Return Spring
6. Shield
7. Main Housing
8. Tab Cap
9. Silicone Lubricant

BD Microtainer® Quikheel™ Lancets

The BD Microtainer® Quikheel™ Lancets are sterile, single-use lancets with a permanently retracting stainless steel blade used for the purpose of obtaining capillary blood specimens for testing utilizing small amounts of blood. The BD Microtainer® Quikheel™ Lancets consist of a front and back housing, a trigger, and a spring onto which a stainless-steel blade is mounted. The stainless-steel blade is non-redeployable to minimize the chance of accidental blade stick injury

and contamination. The device is designed to produce a very rapid triggering of the blade along a predictable path, for low-trauma sampling.

The BD Microtainer® Quikheel™ Lancets are made up of the following key functional components:

1. Front Housing
2. Back Housing
3. Trigger
4. Spring
5. Blade
6. Silicone Lubricant

Substantial Equivalence[1]

The subject and predicate device are substantially equivalent as described in Table 1 and Table 2.

Table 1 BD Microtainer® Contact-Activated Lancet Substantial Equivalence Comparison

Characteristic	Subject Device BD Microtainer® Contact-Activated Lancets	Predicate Device BD Microtainer® Contact-Activated Lancets[2]	Comparison
Device Classification	Class II requiring a 510(k)	Class I 510(k) exempt	The subject BD Microtainer® Contact-Activated Lancets devices were reclassified from Class I exempt devices not requiring a 510(k) to Class II devices requiring a 510(k) under Docket No. FDA-2016-N-0040, effective November 22, 2021.

[1] The term "substantial equivalence" as used in this 510(k) Notification is limited to the definition of substantial equivalence as found in the Federal Food, Drug and Cosmetic Act, as amended and as applied under 21 CFR 807, Subpart E under which a device can be marketed without pre-market approval or reclassification. A determination of substantial equivalency under this notification is not intended to have any bearing whatsoever on the resolution of patent infringement suits or any other patent matters. No statements related to, or in support of substantial equivalence herein shall be construed as an admission against interest under the US Patent Laws or their application by the courts.
[2] Per Docket No. FDA-2016-N-0040, "…any 510(k)-exempt blood lancets legally offered for sale on or before November 22, 2021, can serve as predicates for substantial equivalence purposes."

Characteristic	**Subject Device BD Microtainer® Contact-Activated Lancets**	**Predicate Device BD Microtainer® Contact-Activated Lancets[2]**	**Comparison**
Intended Use / Indications for Use	The BD Microtainer® Contact-Activated Lancet is a sterile, single-use, permanently retracting, lancing device used to perform fingerstick punctures in in adults, adolescents, children, and infants (greater than 6 months of age and 10 kg (22 lbs)). The device is intended to be used by a healthcare professional in a clinical setting to obtain capillary blood specimens for testing utilizing small amounts of blood.	The BD Microtainer® Contact-Activated Lancet is a sterile, single-use, permanently retracting, lancing device used to perform fingerstick punctures in in adults, adolescents, children, and infants. The device is intended to be used by a healthcare professional in a clinical setting to collect capillary blood specimens for diagnostic testing.	The current intended use statement has been converted to an indications for use statement for this initial 510(k) submission. The subject devices' intended use/indications for use also incorporates a minimum age and weight indication consistent with recommendations outlined for fingerpricks in CLSI GP42-A7: Collection of Capillary Blood Specimens, 7th Edition (FDA Recognition Number 7-301) and WHO Guidelines On Drawing Blood: Best Practices In Phlebotomy. The proposed indications for use only add specificity and clarity about what minimum age/weight criteria are appropriate for the fingerstick; the changes do not result in a new intended use.
Target Population	Adults, adolescents, children, and infants (greater than 6 months of age and 10 kg (22 lbs))	Adults, adolescents, children, and infants	This proposed modification incorporates a minimum age and weight indication consistent with recommendations outlined for fingerpricks in CLSI GP42-A7: Collection of Capillary Blood Specimens, 7th Edition (FDA Recognition Number 7-301) and WHO Guidelines On Drawing Blood: Best Practices In Phlebotomy. The proposed indications for use only add specificity and clarity about what minimum age/weight criteria are appropriate for the fingerstick; the changes do not result in a new target population.
Device Design			
Models	366592 366593 366594 366599	366592 366593 366594 366599	Same
Colors	Purple, Pink, Blue	Purple, Pink, Blue	Same
Types of Lancing Device	Needle, Blade	Needle, Blade	Same

Characteristic	**Subject Device BD Microtainer® Contact-Activated Lancets**	**Predicate Device BD Microtainer® Contact-Activated Lancets[2]**	**Comparison**
Needle/Blade Depths	1.5 mm, 1.8 mm, 2.0 mm	1.5 mm, 1.8 mm, 2.0 mm	Same
Needle/Blade Gauges/Widths	30G (0.31 mm), 21G (0.81 mm), 1.5 mm	30G (0.31 mm), 21G (0.81 mm), 1.5 mm	Same
Blood Flows	Low, Medium, High	Low, Medium, High	Same
Device Materials			
Needle Carrier with Protective Tab	Polystyrene	Polystyrene	Same
Main Housing/Tab Cap/Rear Cap	Polypropylene	Polypropylene	Same
Shield	Polyethylene	Polyethylene	Same
Lever Element	Acrylonitrile butadiene styrene (ABS)	Acrylonitrile butadiene styrene (ABS)	Same
Drive Spring	Steel tinned wire	Steel tinned wire	Same
Return Spring	Steel tinned wire	Steel tinned wire	Same
Needle/Blade	Stainless steel	Stainless steel	Same
Needle/Blade Lubricant	Silicone fluid	Silicone fluid	Same
Materials	Compliant with ISO 10993 series	Compliant with ISO 10993 series	Same
Packaging and Sterility			
Sterile Needle Carrier and Needle/Blade	Yes	Yes	Same
Sterility Assurance Level (SAL) 10^{-6}	Yes	Yes	Same
Sterilization Method	Gamma irradiation	Gamma irradiation	Same
Shelf Life	5 years	5 years	Same
Contains Packaging Support Insert	No	Yes	To accommodate the new, standalone IFU created for the subject BD Microtainer® Contact-Activated Lancets, the shelf carton height and the shelf box material density will be increased. The increased shelf carton height and density will also result in the removal of a support insert previously used to hold the box together. Ship testing was conducted to support this packaging change.

Table 2 BD Microtainer® Quikheel™ Lancet Substantial Equivalence Comparison

Characteristic	Subject Device BD Microtainer® Quikheel™ Lancets	Predicate Device BD Microtainer® Quikheel™ Lancets[3]	Comparison
Device Classification	Class II requiring a 510(k)	Class I 510(k) exempt	The subject BD Microtainer® Quikheel™ Lancets devices were reclassified from Class I exempt devices not requiring a 510(k) to Class II devices requiring a 510(k) under Docket No. FDA-2016-N-0040, effective November 22, 2021.
Intended Use / Indications for Use	The BD Microtainer® Quikheel™ Lancet is a sterile, single-use medical device with a push-button activated, permanently retracting blade. The device is intended to be used by healthcare professionals to perform heel sticks in neonates, pre-term (preemie) and full-term infants (non-walking) to obtain capillary blood specimens for testing utilizing small amounts of blood.	The BD Microtainer® Quikheel™ Lancet is a sterile, single-use medical device with a push-button activated, permanently retracting blade. The device is intended to be used by healthcare professionals to perform heel sticks in neonates, pre-term (preemie) and full-term infants (non-walking) to obtain capillary blood specimens for testing utilizing small amounts of blood.	The current intended use statement has been converted to an indications for use statement for this initial 510(k) submission.
Target Population	Neonates, Premature And Full Term Infants	Neonates, Premature And Full Term Infants	Same
Device Design			
Models	368100 368101	368100 368101	Same
Colors	Pink, Teal	Pink, Teal	Same
Incision Depths	0.85 mm, 1.00 mm	0.85 mm, 1.00 mm	Same
Incision Lengths	1.75 mm, 2.50 mm	1.75 mm, 2.50 mm	Same
Blood Flows	Low, High	Low, High	Same
Device Materials			
Blade (infant) and Blade (preemie)	Stainless steel	Stainless steel	Same
Spring	Polycarbonate	Polycarbonate	Same
Trigger	Polycarbonate	Polycarbonate	Same
Internal Trigger/ Spring Lubricant	Silicone Fluid	Silicone Fluid	Same
Housing (front/back)	Polystyrene	Polystyrene	Same
Materials	Compliant with ISO 10993 series	Compliant with ISO 10993 series	Same

[3] Per Docket No. FDA-2016-N-0040, "…any 510(k)-exempt blood lancets legally offered for sale on or before November 22, 2021, can serve as predicates for substantial equivalence purposes."

Characteristic	Subject Device BD Microtainer® Quikheel™ Lancets	Predicate Device BD Microtainer® Quikheel™ Lancets[3]	Comparison
Packaging and Sterility			
Sterile	Yes	Yes	Same
Sterility Assurance Level (SAL) 10^{-6}	Yes	Yes	Same
Sterilization Method	Gamma irradiation	Gamma irradiation	Same
Shelf Life	5 years	5 years	Same

As provided in Table 1 and Table 2, the subject devices and their respective predicates use the same operating principles, incorporate the same detailed designs, are manufactured from the same materials, are sterilized using the same method (gamma irradiation) with the same SAL of 10^{-6}, use the same technological characteristics, have identical shelf lives (5 years), are packaged using similar sterile barrier and case materials, and have the same intended use. The new indications for use established as part of this 510(k) submission align with the respective predicates' intended uses.

The subject BD Microtainer® Contact-Activated Lancets' intended use incorporates a minimum age and weight indication consistent with recommendations outlined for fingerpricks in CLSI GP42-A7: Collection of Capillary Blood Specimens, 7th Edition (FDA Recognition Number 7-301) and WHO Guidelines On Drawing Blood: Best Practices In Phlebotomy. The proposed indications for use only add specificity and clarity about what minimum age/weight criteria are appropriate for the fingerstick; the changes do not result in a new intended use.

The subject and predicate BD Microtainer® Quikheel™ Lancets have the same intended use. The current intended use statement has been converted to an indications for use statement for this initial 510(k) submission.

Performance Testing – Bench Summary

Device, biocompatibility, and sterilization testing were conducted on the subject devices to validate that the devices perform as intended over the course of the product shelf life. Results of testing demonstrate acceptable performance for the subject devices.

Performance Testing – Animal Summary

Per the blood lancets classification regulation (21 CFR 878.4850(a)), animal testing is not required for the clearance of the subject devices. Therefore, BD is not submitting any animal performance data in support of this 510(k) submission.

Performance Testing – Clinical Summary

Per the blood lancets classification regulation (21 CFR 878.4850(a)), clinical testing is not required for the clearance of the subject devices. Therefore, BD is not submitting any clinical performance data in support of this 510(k) submission.

Conclusion

In summary, the BD Microtainer® Contact-Activated Lancets have the same intended use as their predicate device, and a new indication for use statement which aligns to this intended use. The BD Microtainer® Quikheel™ Lancets have the same intended use as their predicate device, and the indications for use statement is identical to the predicate's intended use statement. In addition, the BD Microtainer® Contact-Activated Lancets and BD Microtainer® Quikheel™ Lancets have the same technological characteristics and principles of operation as their respective predicates. Performance testing confirms that the subject devices perform as intended and are as safe and effective as their respective predicate devices.

The subject devices were reclassified from Class I exempt devices not requiring a 510(k) to Class II devices requiring a 510(k) under Docket No. FDA-2016-N-0040, effective November 22, 2021. This 510(k) serves as BD's initial 510(k) submission for these devices in response to the reclassification and 510(k) requirement.

Based on information provided, the proposed devices are substantially equivalent to their respective predicate devices.