June 22, 2022

Qlicksmart Pty Ltd.
Carlos Castellanos
Quality Assurance Manager
Level 1, 148 Boundary Street, West End
Brisbane, Queensland 4101
Australia

Re: K213274
Trade/Device Name: Qlicksmart BladeFlask UNIVERSAL
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: Class II
Product Code: MMK
Dated: September 30, 2021
Received: September 30, 2021

Dear Carlos Castellanos:

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,

for Clarence W. Murray, III, Ph.D.
Assistant Director
DHT4B: Division of Infection Control
and Plastic 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)*
K213274

Device Name
Qlicksmart BladeFlask PLUS

Indications for Use *(Describe)*
The Qlicksmart BladeFlask PLUS is a single-use sharps container with a scalpel blade removal function intended to permit the safe removal of scalpel blades from most currently available scalpel handles and contain the blade immediately upon removal to eliminate the need for further handling prior to be disposed as medical waste while allowing the user to monitor its use to see when it is becoming full and will need changing. Scalpel handles compatible with the Qlicksmart BladeFlask PLUS include:

- Swann Morton sizes 3, 4, 5, 6, 7, 8, and 9
- Lawton size 4
- Martin sizes 3, 4, and 7
- Aesculap sizes 3, 4, 6, and 7
- Sayco sizes 3, 4, and 5
- Smic sizes 3 and 4
- Nopa sizes 3 and 4
- AB Stainless size 4
- Lance sizes 3 and 4
- Pro-Med sizes 3 and 4
- Paragon sizes 3 and 4
- Rocket size 5
- Conqueror size 3
- Feather sizes 3, 4, and 7
- LRI sizes 3 and 4
- Generic handle size 4
- L-dent
- Medesy size 5
- Jakobi size 4
- CS size 5
- Helmut Zepf

Scalpel handles known to be incompatible with the Qlicksmart BladeFlask PLUS include:

- Beaver type handles
- Disposable handles

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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K213274 510(k) SUMMARY

I. SUBMITTER

Qlicksmart Pty Ltd
Level 1, 148 Boundary Street
West End, QLD, 4101, Australia
Phone: +61 7 3844 1182
Contact Person: Michael Sinnott
Date Prepared: 17 June 2022

II. SUBJECT DEVICE

Trade Name of Device: Qlicksmart BladeFlask PLUS
Common or Usual Name: Sharps Container with a scalpel blade removing function
Classification Name: Hypodermic single lumen needle (21 CFR 880.5570)
Regulatory Class: II
Product Code: MMK

III. PREDICATE DEVICE

Predicate Device 510(k) application number: K983367
Original Name of the legally marketed predicate device was QLICKSMART®,
Current trading name of the legally marketed predicate device: Qlicksmart BladeFLASK

IV. DEVICE DESCRIPTION

The Qlicksmart BladeFlask PLUS is a single-use sharps container with a scalpel blade removal function that is used under non-sterile conditions. The Qlicksmart BladeFlask PLUS removes scalpel blades from scalpel handles in a single-handed action and then immediately contains the used scalpel blade inside the Qlicksmart BladeFlask PLUS. The handle is intended to be used to dispose the entire container as hazardous waste when full (100 removed blades and shut-off system is activated) and the device is not intended to be reprocessed.

The Qlicksmart BladeFlask PLUS combines a hard plastic sharps container with an internal blade remover mechanism made of hard plastic and hardened steel parts.

It is approximately (13.5 cm) tall by (9.1 cm) wide by (12.3 cm) deep. It weighs less than 250gm per unit when empty. It is red in color. It is labelled as shown on the samples provided with this application.

V. INDICATIONS FOR USE

The Qlicksmart BladeFlask PLUS is a single-use sharps container with a scalpel blade removal function intended to permit the safe removal of scalpel blades from most currently available scalpel handles and contain the blade immediately upon removal to eliminate the need for further handling

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prior to be disposed as medical waste while allowing the user to monitor its use to see when it is becoming full and will need changing. Scalpel handles compatible with the Qlicksmart BladeFlask PLUS include:

- Swann Morton sizes 3, 4, 5, 6, 7, 8, and 9
- Lawton size 4
- Martin sizes 3, 4, and 7
- Aesculap sizes 3, 4, 6, and 7
- Sayco sizes 3, 4, and 5
- Smic sizes 3 and 4
- Nopa sizes 3 and 4
- AB Stainless size 4
- Lance sizes 3 and 4
- Pro-Med sizes 3 and 4
- Paragon sizes 3 and 4
- Rocket size 5
- Conqueror size 3
- Feather sizes 3, 4, and 7
- LRI sizes 3 and 4
- Generic handle size 4
- L-dent
- Medesy size 5
- Jakobi size 4
- CS size 5
- Helmut Zepf

Scalpel handles known to be incompatible with the Qlicksmart BladeFlask PLUS include:

- Beaver type handles
- Disposable handles

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

A sharps container with a scalpel blade removal function that is used under non-sterile conditions is the technological principle for both the subject and predicate devices. It is based on the use of a mechanism for removing scalpel blades from scalpel handles in a single-handed action and then immediately contains the used scalpel blade inside the device.

Characteristics	**Subject Device**	**Predicate Device**	**Comparison**
Trade Name	**Qlicksmart BladeFlask PLUS (Proposed Trade Name)**	**QLICKSMART® [Original Trade Name used in the premarket 510(k) notification] Qlicksmart BladeFLASK (Current Trade Name)**	**N/A**
Product Code	**MMK**	**MMK**	**Identical**
510(k) Number	**K213274**	**K983367**	**N/A**
Regulation Number	**21 CFR 880.5570**	**21 CFR 880.5570**	**Identical**

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Characteristics	Subject Device	Predicate Device	Comparison
Intended use	The Qlicksmart BladeFlask PLUS is a sharps container with a scalpel blade removal function. The Qlicksmart BladeFlask PLUS is a single-use sharps container with a scalpel blade removal function that is used under non-sterile conditions. The Qlicksmart BladeFlask PLUS removes scalpel blades from scalpel handles in a single-handed action and then immediately contains the used scalpel blade inside the Qlicksmart BladeFlask PLUS. The handle is intended to be used to dispose the entire container as hazardous waste when full (100 removed blades and shut-off system is activated) and the device is not intended to be reprocessed.	The QLICKSMART® is a sharps container with a scalpel blade removal function. The QLICKSMART® is a single-use sharps container with a scalpel blade removal function that is used under non-sterile conditions. The QLICKSMART® removes scalpel blades from scalpel handles in a single-handed action and then immediately contains the used scalpel blade inside the QLICKSMART®. The handle is intended to be used to dispose the entire container as hazardous waste when full (100 removed blades and shut-off system is activated) and the device is not intended to be reprocessed.	Identical
Indications for use	The Qlicksmart BladeFlask PLUS is a single-use sharps container with a scalpel blade removal function intended to permit the safe removal of scalpel blades from most currently available scalpel handles and contain the blade immediately upon removal to eliminate the need for further handling prior to be disposed as medical waste while allowing the user to monitor its use to see when it is becoming full and will need changing. Scalpel handles compatible with the Qlicksmart BladeFlask PLUS include: • Swann Morton sizes 3, 4, 5, 6, 7, 8, and 9 • Lawton size 4 • Martin sizes 3, 4, and 7 • Aesculap sizes 3, 4, 6, and 7 • Sayco sizes 3, 4, and 5 • Smic sizes 3 and 4 • Nopa sizes 3 and 4 • AB Stainless size 4	The QLICKSMART® is a single-use sharps container with a scalpel blade removal function intended to permit the safe removal of scalpel blades commonly available scalpel handles and contain the blade immediately upon removal to eliminate the need for further handling prior to be disposed as medical waste while allowing the user to monitor its use to see when it is becoming full and will need changing. Scalpel handles compatible with Qlicksmart® include: • Swann Morton sizes 3, 4, 7, and 9 • Lawton sizes 3 and 4 • Martin sizes 3, 4, and 7 • Aesculap sizes 3, 3L, 4, and 7 • Sayco sizes 3, 4, and 5 • Smic sizes 3 and 4 • Nopa sizes 3 and 4 • AB Stainless size 4 • Lance sizes 3 and 4 • Pro-Med sizes 3 and 4	Similar. The subject device removes scalpel blades from size No. 3, 4, 5, 6, 7, 8 & 9 scalpel handles whereas the predicate device removes scalpel blades from size No. 3, 4, 7 & 9 scalpel handles. The subject device removes scalpel blades up to a maximum blade size #60B whereas the predicate device removes scalpel blades up to a maximum blade size #36.

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Characteristics	Subject Device	Predicate Device	Comparison
	• Lance sizes 3 and 4 • Pro-Med sizes 3 and 4 • Paragon sizes 3 and 4 • Rocket size 5 • Conqueror size 3 • Feather sizes 3, 4, and 7 • LRI sizes 3 and 4 • Generic handle size 4 • L-dent • Medesy size 5 • Jakobi size 4 • CS size 5 • Helmut Zepf Scalpel handles known to be incompatible with the Qlicksmart BladeFlask PLUS include: • Beaver type handles • Disposable handles	• Paragon sizes 3 and 4 • Rocket size 5 • Conqueror size 3 • Feather size 7 • LRI size 4 • Generic handle size 4 • Jakobi size 4 Scalpel handles known to be incompatible with the Qlicksmart® include: - Barron Handle - Beaver type handles - Disposable handles	
Conditions of Use	Non-Sterile, Single use, Non-reusable when full with appx 100 blades. Disposal as Hazardous Waste	Non-Sterile, Single use, Non-reusable when full with appx 100 blades. Disposal as Hazardous Waste	Identical
Anatomical Site	Not applicable	Not applicable	Identical
Where used	General hospitals and other clinical settings. It can be fixed in the correct position by a hardware bracket or sticky tape.	General hospitals and other clinical settings. It can be fixed in the correct position by a hardware bracket or sticky tape.	Identical
Materials of Construction	The flask is a hard plastic (ABS), opaque and red in color, fully enclosed single-use sharps container. The minimum thickness of the flask is 1.5mm, no value below this is permitted. The two parts of the container have been designed and mechanically sealed to ensure the container is leak proof.	The flask is a hard plastic (ABS), opaque and red in color, fully enclosed single-use sharps container. The minimum thickness of the flask is 1.5mm, no value below this is permitted. The two halves are contiguously ultrasonically welded together.	Similar. The subject device is mechanical sealed to ensure the container is leak proof whereas the predicate device is ultrasonically welded two keep the two halves together.

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Characteristics	Subject Device	Predicate Device	Comparison
Weights and Dimensions	• Approximately (13.5cm) tall by (9.1 cm) wide by (12.3) cm) deep. • The volume is sufficient to hold 100 of the largest scalpel blades tested. • Weights less than 250gm per unit when empty	• Approximately (15 cm) tall by (10 cm) wide by (13 cm) deep. • The volume is 14.2ml, sufficient to hold 100 of the largest scalpel blades tested. • Weights less than 250gm per unit when empty	Similar. The subject device is slightly smaller than the predicate device. However, the volume is sufficient to hold 100 of the largest scalpel blades tested.
Technological Characteristics	A scalpel blade removal mechanism that: • Contains a mechanism, that strips scalpel blades from scalpel handles; that is, made up of plastic and hardened steel • It incorporates a mechanical counting mechanism and automatic mechanical shut off system that closes the unit once the unit has removed around 100 blades and thus prevents overfilling • The mechanism is designed to be operated using one hand. • Removes scalpel blades from size No. 3, 4, 5, 6, 7, 8, & 9 scalpel handles • Removes scalpel blades up to a maximum blade size #60B. • Is not to be used for Beaver handles, or Disposable handles.	A scalpel blade removal mechanism that: • Contains a mechanism, that strips scalpel blades from scalpel handles; that is, made up of plastic and hardened steel • It incorporates a mechanical counting mechanism and automatic mechanical shut off system that closes the unit once the unit has removed around 100 blades and thus prevents overfilling • The mechanism is designed to be operated using one hand. • Removes scalpel blades from size No. 3, 4, 7, & 9 scalpel handles • Removes scalpel blades up to a maximum blade size #36. • Is not to be used for Baron handles, Beaver handles, or Disposable handles.	Similar. The subject device removes blades from additional handle types and additional types of blades. Differences in operational range addressed by the performance testing. No new issues of safety raised.
Shelf Life	Not applicable	Not applicable	Identical
Performance Specifications	It underwent the following tests conducted by Falcon Test Engineers, a NATA (National Association of Testing Authorities) approved laboratory:	It underwent the following tests conducted by ETRS, a NATA (National Association of Testing Authorities) approved laboratory: **Performance Tests**	Additional performance testing for subject device based upon the recognize standard ISO

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Characteristics	Subject Device	Predicate Device	Comparison
	Performance Tests The performance tests were conducted in accordance with the AS 4031-1992 "Non-reusable containers for the collection of sharp medical items used in health care areas". These tests included: • Impact resistance, integrity of closure and leakage as per Appendix B of AS 4031:1992 • Handle integrity as per Appendix A of AS 4031:1992 • Toppling resistance as per Appendix D of AS 4031:1992 Resistance to penetration as per Appendix C of AS 4031:1992 Additional performance tests were conducted in accordance with the Recognized Standard ISO 23907-1 First edition 2019-01, "Sharps injury protection - Requirements and test methods - Sharps containers". These tests included • Container Stability • Strength of Handle • Resistance to Penetration • Resistance to Damage and Leakage after Dropping • Resistance to Spillage by Toppling	The performance tests were conducted in accordance with the AS 4031-1992 "Non-reusable containers for the collection of sharp medical items used in health care areas". These tests included: • Impact resistance, integrity of closure and leakage as per Appendix B of AS 4031:1992 • Handle integrity as per Appendix A of AS 4031:1992 • Toppling resistance as per Appendix D of AS 4031:1992 • Resistance to penetration as per Appendix C of AS 4031:1992	23907-1 did not raise new issues of safety or efficacy.
Mechanical and Functional Tests	The mechanical and functional tests were conducted in accordance with the ETRS Scalpel Blade Removal Testing Protocols that were specifically designed in collaboration	The mechanical and functional tests were conducted in accordance with the ETRS Scalpel Blade Removal Testing Protocols that were specifically designed in collaboration	The subject device passed all testing as the predicate device did.

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Characteristics	Subject Device	Predicate Device	Comparison
	with Qlicksmart for this type of devices. The battery of testing included the following tests: • Blade removal function • Counting mechanism activation • Automatic shut-off mechanism activation • It can be installed into the bracket with reasonable force • Uses force to strip a scalpel blade from a scalpel handle that is less that the force required to uninstall the device from the bracket • Incorrect insertion of the scalpel handle	with Qlicksmart for this type of devices. The battery of testing included the following tests: • Blade removal function • Counting mechanism activation • Automatic shut-off mechanism activation • It can be installed into the bracket with reasonable force • Uses force to strip a scalpel blade from a scalpel handle that is less that the force required to uninstall the device from the bracket • Incorrect insertion of the scalpel handle	
Transportation Tests	Tests for the subject device were conducted in accordance with the United Nations Recommendations on the Transport of Dangerous Goods 21st Edition 6.1.5.3 and 6.1.5.6. Falcon Test Engineers found that Qlicksmart BladeFlask PLUS successfully passed all these tests The battery of testing included the following tests: • Drop Test • Stacking Test	Tests for the subject device were conducted in accordance with the United Nations Recommendations on the Transport of Dangerous Goods 21st Edition 6.1.5.3 and 6.1.5.6. Falcon Test Engineers found that Qlicksmart BladeFlask PLUS successfully passed all these tests The battery of testing included the following tests: • Drop Test • Stacking Test	The subject device passed all testing as the predicate device did.

VII. SUMMARY OF NON-CLINICAL TESTING

PERFORMANCE DATA

Performance testing was provided to demonstrate that the Qlicksmart BladeFlask PLUS met the acceptance criteria or specifications found in the standards and guidance provided below.

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PERFORMANCE TESTING

TEST METHOD or STANDARD	TEST PURPOSE	ACCEPTANCE CRITERIA	RESULTS
ISO 23907-1	Test Container Stability	The container shall not topple over when tested	PASS
ISO 23907-1	Test Strength of Handle	The handle shall not break or detach during testing	PASS
ISO 23907-1	Test Resistance to Penetration	The force needed to penetrate test specimens shall be minimum of 16N and an average of 18N or greater	PASS
ISO 23907-1	Test Resistance to Damage and Leakage after Dropping	No evidence of leakage and no breach of the sharp's containment area	PASS
ISO 23907-1	Test Resistance to Spillage by Dropping	No evidence that the performance or function of the container has been compromised, closure remains intact	PASS
Blade Removal Qlicksmart In -house Testing	Test Blade Removal Performance	If one scalpel blade is not removed from a particular combination, that particular handle and blade combination will be not approved for being used with the BladeFlask PLUS and declared as incompatible	The results shows that all the different combinations of known handles and blades were removed in a safe and effective manner using only one hand. Except for Beaver and disposable handles.
Counting mechanism activation Qlicksmart In -house Testing	Test Counting Accuracy	The counter should read to an accuracy of 100±5 scalpel blades to be inserted before the full sign appears	PASS
Automatic shut-off mechanism activation Qlicksmart In -house Testing	Test Performance of Automatic shut-off mechanism activation	The counter should activate with an accuracy of 100± 5 scalpel blades to be inserted before the automatic shut-off mechanism is activated	PASS
Bracket Suitability Test Qlicksmart In -house Testing	Test of Bracket Functional Performance	The force required to install or remove the container from the bracket must be more than the force in Newtons to insert or retrieve the scalpel handles into the container and less than 90 Newtons which will be a safety amount of force for the user to install or remove the container	Force required to install and remove the container 75.30 Newtons

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TEST METHOD or STANDARD	TEST PURPOSE	ACCEPTANCE CRITERIA	RESULTS
Scalpel Removal Test Qlicksmart In -house Testing	Test of Scalpel Removal Functional Performance	The force required to insert or retrieve the scalpel handle into or from the container must be less than the force in Newtons to remove the container from the bracket	Force required to insert the scalpel handle is 22.50 Newtons and to remove the scalpel handle is 23.75 Newtons
Scalpel Insertion Test Qlicksmart In -house Testing	Test of Scalpel Insertion Functional Performance	The device is not jammed, and the device is not become non-functional should the scalpel handle be inserted incorrectly	PASS
Drop Test The United Nations Recommendations on the Transport of Dangerous Goods 21st Edition 6.1.5.3	Test of Product Functional Performance	No rupture is permitted in packaging which would be permit the spillage of loose explosive substances or articles from the outer packaging	PASS
Stacking Test The United Nations Recommendations on the Transport of Dangerous Goods 21st Edition 6.1.5.3	Test of Product Functional Performance	No test sample may leak. No test sample may show any deterioration which could adversely affect transport safety or any distortion liable to reduce its strength or cause instability in stacks of packages	PASS

The test results demonstrate the subject device complies with the applicable requirements.

CLINICAL TEST

Not applicable.

VIII. CONCLUSIONS

The non-clinical data demonstrate that the subject device, Qlicksmart BladeFlask PLUS, is as safe, as effective, and performs as well as or better than the predicate device, Qlicksmart BladeFLASK with Premarket Submission Number, K983367.