January 16, 2024

Dentsply Sirona
Rebecca Sporer
Principle Regulatory Affairs Specialist
221 West Philadelphia Street
Suite 60W
York, Pennsylvania 17401

Re: K231144
Trade/Device Name: Washtrays
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: Class II
Product Code: KCT,
Dated: December 11, 2023
Received: December 12, 2023

Dear Rebecca Sporer:

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.

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,

Colin O'neill -S

Colin O'Neill, M.B.E.
Assistant Director
DHT6B: Division of Spinal Devices
OHT6: Office of Orthopedic 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)*
K231144

Device Name
Washtrays

Indications for Use *(Describe)*
Washtrays are intended for organizing, cleaning, sterilizing and storing of instruments.
The Washtrays are not intended to maintain sterility and are to be used in conjunction with a legally marketed, validated sterilization pouch or a sterilization container.

Sterilization parameters
Pre-vacuum Steam at 132 °C (270 °F) for 4 minutes with a 20-minute dry time.
Do not exceed the worst-case validated maximum load:

Product name	Article Number	Dimensions Length x Width x Height (in)	Maximum Load (g)	Vent to Volume Ratio (in^{-1})
OmniTaper Washtray	68015271	10.83 X 6.93 X 2.32	1107.3	2.54
OmniTaper Washtray GS	68015354		1107.3	2.54
PrimeTaper Washtray	68015323		1107.3	2.54
PrimeTaper Washtray GS	68017267		1107.3	2.54
Washtray Astra Tech Implant System EV	31071000		1107.3	2.54
Washtray GS Astra Tech Implant System EV	31071020		1107.3	2.54
Ankylos Washtray	31036600		1107.3	2.54

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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Dentsply Sirona Inc.
221 West Philadelphia Street, Suite 60W
York, PA 17401

SECTION 5. 510(k) SUMMARY
Washtrays
K231144

5.1 Submitter Information:

Dentsply Sirona Inc.

221 West Philadelphia Street
Suite 60W
York, PA 17401

Contact Person: Rebecca Sporer
Telephone Number: 717-353-1150
Fax Number: 717-849-4343
Email: corporate-ra@dentsplysirona.com

Date Prepared: January 12, 2024

5.2 Device Name:

- Proprietary Name: Washtrays
- Classification Name: Sterilization Wrap Containers, Trays, Cassettes & Other Accessories
- CFR Number: 21 CFR 880.6850
- Device Class: Class II
- Product Code: KCT

5.3 Predicate Device:
The predicate device identified is the following:

Predicate Device Name	NobelSpeedy® Groovy / Brånemark System® Mk III TiUnite / Replace SelectTM TC PureSet™ Tray
510(k)	K212932
Company Name	Nobel Biocare AB
Classification Name:	Sterilization Wrap Containers, Trays, Cassettes & Other Accessories
CFR Number:	21 CFR 880.6850
Device Class:	Class II
Product Code:	KCT

5.4 Device Description:

The proposed Washtrays are used to store and organize dental implant surgical instruments needed during implant surgery, as well as hold instruments during cleaning and sterilization. The Washtrays are not intended to maintain sterility and are to be used in conjunction with a legally marketed, validated sterilization pouch or sterilization container.

The proposed Washtrays consist of a stainless-steel perforated tray equipped with baskets and a lid with a handle. The large basket comprises instrument holders inserted in an anodized aluminum alloy Overlay printed with visual symbols for correct positioning of the designated instruments such as drills and taps.

The designated instruments are placed in the Overlay in the Instrument holders which are made with PEEK and have a stainless steel spring to hold the instruments in place. The Overlay guides the user through the surgical protocol for implant placement. The small basket with its own small lid and silicone mat inside is used to store the instruments which can be disassembled prior to cleaning. The metal grid base has silicone feet to prevent the Washtrays from slipping/sliding when placed on a surface.

The outer dimensions for all Washtrays is the same, 10.83 x 6.93 x 2.32 inches. The inner arrangement of the baskets varies between the Washtrays. Table 5.1 gives an overview of all Washtray configurations.

Table 5.1: Washtray configurations

Product name	Part number	Dimensions Length x Width x Height (in)	Max load (g)	Vent to volume ratio (in^{-1})
OmniTaper Washtray	68015271	10.83 X 6.93 X 2.32	1107.3	2.54
OmniTaper Washtray GS	68015354		1107.3	2.54
PrimeTaper Washtray	68015323		1107.3	2.54
PrimeTaper Washtray GS	68017267		1107.3	2.54
Washtray Astra Tech Implant System® EV	31071000		1107.3	2.54
Washtray GS Astra Tech Implant System® EV	31071020		1107.3	2.54
Ankylos Washtray	31036600		1107.3	2.54

5.5 Indications for Use

The Washtrays are intended for organizing, cleaning, sterilizing and storing of instruments.

The Washtrays are not intended to maintain sterility and are to be used in conjunction with a legally marketed, validated sterilization pouch or a sterilization container.

Sterilization parameters

Pre-vacuum Steam at 132°C (270°F) for 4 minutes with a 20-minute dry time.

Do not exceed the worst-case validated maximum load:

Product name	Article Number	Dimensions Length x Width x Height (in)	Maximum Load (g)	Vent to Volume Ratio (in^{-1})
OmniTaper Washtray	68015271	10.83 X 6.93 X 2.32	1107.3	2.54
OmniTaper Washtray GS	68015354		1107.3	2.54
PrimeTaper Washtray	68015323		1107.3	2.54
PrimeTaper Washtray GS	68017267		1107.3	2.54
Washtray Astra Tech Implant System® EV	31071000		1107.3	2.54
Washtray GS Astra Tech Implant System® EV	31071020		1107.3	2.54
Ankylos Washtray	31036600		1107.3	2.54

5.6 Comparison of Technological Characteristics

An overview of the similarities and differences between the proposed and predicate device is given in Table 5.6.1.

The proposed Washtrays and the predicate device NobelSpeedy® Groovy / Brånemark System® Mk III TiUnite / Replace SelectTM TC PureSet™ Tray (K212932) have the same intended use, same sterilization method (Pre-Vacum) and parameters, and are made of the same materials (stainless steel, silicone and PEEK). The proposed Washtrays have the same configuration and perforation, with an evenly distributed hole pattern, similar to the predicate device.

The use of the Washtrays has been validated through performance, biocompatibility and sterilization testing. There are only minor differences between the proposed and the predicate device. The height of the proposed Washtrays is slightly different when compared to the predicate device. The proposed Washtrays are larger in height than the predicate device which results in a difference in the vent to volume ratio. When compared to the predicate device, the proposed Washtrays have a larger maximum sterilization load. The minor differences in dimension (height), vent to volume ratio, and weight do not impact the sterility, as substantial equivalence was demonstrated through sterilization validation testing which confirms a SAL level of 10^{-6}.

To maintain sterility the proposed Washtrays are to be used in conjunction with a legally marketed, validated sterilization pouch or a sterilization container. In addition to this, the predicate device can also be used in conjunction with a legally marketed wrap. The proposed Washtrays sterilization validation confirms that the dry time is the same when using a sterilization container compared to the recommended wrap for the predicate device, and that a SAL level of 10^{-6} is achieved.

The proposed device is only validated for pre-vacuum steam sterilization. Unlike the predicate device, the proposed Washtrays are not intended to be sterilized via gravity displacement and therefore this method is not validated nor referenced in the Instructions for Use.

Table 5.6.1: Technological Characteristics Comparison Table

<table>
<tr><th>Element</th><th>Proposed Device
Washtrays
(K231144)</th><th>Predicate Device
NobelSpeedy® Groovy / Brånemark System® Mk III TiUnite / Replace SelectTM TC PureSet™ Tray
(K212932)</th><th>Discussion</th></tr>
<tr><td>Indications for Use</td><td>The Washtrays are intended for organizing, cleaning, sterilizing and storing of instruments.

The Washtrays are not intended to maintain sterility and are to be used in conjunction with a legally marketed, validated sterilization pouch or a sterilization container.

Sterilization parameters
Pre-vacuum Steam at 132°C (270°F) for 4 minutes with a 20 minute dry time.
Do not exceed the worst-case validated maximum load:
<table>
<tr><th>Product name</th><th>Article Number</th><th>Dimensions (Length x Width x Height)</th><th>Maximum Load (g)</th><th>Vent to Volume Ratio (in^{-1})</th></tr>
<tr><td>OmniTaper Washtray</td><td>68015271</td><td rowspan="6">10.83 in x 6.93 in x 2.32 in</td><td>1107.3</td><td>2.54</td></tr>
<tr><td>OmniTaper Washtray GS</td><td>68015354</td><td>1107.3</td><td>2.54</td></tr>
<tr><td>PrimeTaper Washtray</td><td>68015323</td><td>1107.3</td><td>2.54</td></tr>
<tr><td>PrimeTaper Washtray GS</td><td>68017267</td><td>1107.3</td><td>2.54</td></tr>
<tr><td>Washtray Astra Tech Implant System® EV</td><td>31071000</td><td>1107.3</td><td>2.54</td></tr>
<tr><td>Washtray GS Astra Tech</td><td>31071020</td><td>1107.3</td><td>2.54</td></tr>
</table>
</td><td>Nobel Biocare PureSet Trays are used in healthcare facilities to store and organize Nobel Biocare surgical/prosthetic instruments and components during cleaning/sterilization and during implant/prosthetic treatment.
Nobel Biocare PureSet Trays are not intended on their own to maintain sterility; they are intended to be used in conjunction with a legally marketed, validated, FDA cleared sterilization container, sterilization pouch, or sterilization wrap.

Sterilization validations for the worst-case PureSet Tray included surgical instruments such as torque wrenches, implant drivers, direction indicators, drills, screw taps, screwdrivers, and irrigation needles. The PureSetTrayswere validated for a maximum load of 1635 grams
(Trefoil PureSet Tray), 1122 grams (NobelActive / NobelParallel CC PureSet Tray), 1063 grams (NobelReplace CC PureSet Tray), 454 grams (Nobel Biocare N1™ PureSet Tray), 486 grams (Prosthetic PureSet Tray), 1143 grams (NobelActive Guided PureSet Tray), 1146 grams (NobelParallel CC Guided PureSet Tray), 1176 grams (NobelReplace CC Guided PureSet Tray), and 1035 grams (NobelSpeedy® Groovy / Brånemark System® Mk III TiUnite / Replace SelectTM TC PureSet™ Tray).</td><td>Same uses but the proposed Washtrays are validated for one sterilization parameter.</td></tr>
</table>

<table>
<tr><th>Element</th><th>Proposed Device
Washtrays
(K231144)</th><th>Predicate Device
NobelSpeedy® Groovy / Brånemark System® Mk III TiUnite / Replace SelectTM TC PureSet™ Tray
(K212932)</th><th>Discussion</th></tr>
<tr><td></td><td>
<table>
<tr><td>Implant System® EV</td><td></td><td></td><td></td><td></td></tr>
<tr><td>Ankylos Washtray</td><td>31036600</td><td></td><td>1107.3</td><td>2.54</td></tr>
</table>
</td><td>
<table>
<tr><td>Method</td><td colspan="2">Steam Sterilization (Moist Heat Sterilization
for Wrapped Instruments)</td></tr>
<tr><td>Cycle</td><td>Dynamic-Air-Removal (fractionated vacuum)</td><td>Gravity-Displacement</td></tr>
<tr><td>Temparature</td><td>132°C
(270°F)</td><td>132°C
(270°F)</td></tr>
<tr><td>Exposure time for the single-use pouched device</td><td>4 minutes
(full-cycle)</td><td>15 minutes
(full-cycle)</td></tr>
<tr><td>Minimum drying times</td><td>20 minutes</td><td>30 minutes</td></tr>
</table>
</td><td></td></tr>
<tr><td>Intended Use</td><td>The Washtray are intended for organizing, cleaning, sterilizing and storing of instruments.</td><td>The Nobel Biocare PureSet Tray is intended for use in healthcare facilities to store and organize Nobel Biocare surgical instruments and components during cleaning/sterilization and during implant/prosthetic treatment. The Nobel Biocare PureSet Trays are not intended on their own to maintain sterility; it is intended to be used in conjunction with a legally marketed, validated, FDA-cleared sterilization container, sterilization pouch, or sterilization wrap. Sterilization validations for the worst-case Nobel Biocare PureSet Tray (276.1 mm x 176 mm x 78 mm) included surgical instruments such as torque wrenches, implant drivers, direction indicators, drills, etc.</td><td>Similar
Predicate device shares the same device functionality of organizing, cleaning, sterilizing and storing instruments as proposed device.</td></tr>
<tr><td>Manufacturer</td><td>Dentsply Sirona</td><td>Nobel Biocare AB</td><td>Different</td></tr>
<tr><td>Product code</td><td>KCT</td><td>KCT</td><td>Same</td></tr>
<tr><td>Device class</td><td>II</td><td>II</td><td>Same</td></tr>
<tr><td>Classification Name</td><td>Sterilization Wrap Containers, Trays, Cassettes & Other Accessories</td><td>Sterilization Wrap Containers, Trays, Cassettes & Other Accessories</td><td>Same</td></tr>
</table>

Element	Proposed Device Washtrays (K231144)	Predicate Device NobelSpeedy® Groovy / Brånemark System® Mk III TiUnite / Replace SelectTM TC PureSet™ Tray (K212932)	Discussion
CFR Number and Name	21 CFR 880.6850, Sterilization wrap	21 CFR 880.6850, Sterilization wrap	Same
Dimensions	10.83 in x 6.93 in x 2.32 in (276.1mm in x 176mm in x 59 mm)	276.1mm x 176mm x 47mm	Different
Tray Perforation	Evenly distributed hole pattern	Evenly distributed hole pattern	Same
Configuration	Perforated metal grid base with baskets and lids, instrument holders and outer lid with handle.	Perforated bases, lids and PEEK Luvocom grommets	Same
Materials	Washtray: • Metal Grid Base-Stainless steel 1.4301 • Metal grid base feet-Silicone • Large basket - Stainless steel 1.4303 • Small Basket - Stainless steel 1.4303 • Lid with Handle-Stainless Steel 1.4310 • Silicone mat (inside the small basket)-Silicone • Instrument Holders – PEEK with stainless steel spring • Overlay – Anodized aluminum	• PureSet Tray: o Tray (including basket / lid / handle / sheet metal parts): Stainless steel (1.4301, 1.4303, 1.4310) o Grommets: PEEK, Stainless steel 1.4310 o Tray / Basket Closures: Stainless steel 1.4310, PEEK o Feet: Silicone elastomer • PureSet Tray Plate: Anodized aluminum	Same
Mass of maximum sterilization load	1107.3g	1035g	Different
Volume to Vent Ratio	2.54 in^{-1} (10.36 mm^{-1})	29.4	Different
Sterility	Non-sterile	Non-sterile	Same
Sterilization Method	Moist heat (steam)	Moist heat (steam)	Same

Element	Proposed Device Washtrays (K231144)	Predicate Device NobelSpeedy® Groovy / Brånemark System® Mk III TiUnite / Replace SelectTM TC PureSet™ Tray (K212932)	Discussion
Sterilization Parameters	Pre vacuum, At 132°C for 4 minutes with a 20 minute dry time	• Pre-Vacuum: o Temp 132°C (270º F) o Exposure Time 4 minutes o Pre-vacuum: 4 times < 60 mbar o Drying Time: 20 minutes o Cooling Time: 30 minutes total • Gravity Displacement: o Temp 132°C (270º F) o Exposure Time: 15 minutes o Pre-vacuum: N/A o Drying Time: 30 minutes o Cooling Time: 30 minutes total	Same.
Sterile barrier	FDA cleared sterilization pouch/container	FDA cleared sterilization wrap/pouch	Different
Reusable	Yes	Yes	Same
Supplier	Aesculap AG	Aesculap AG	Same

5.7 Non-Clinical Performance Data

The proposed Washtrays are reusable devices provided non-sterile which need to be end user cleaned and sterilized. Sterilization of the proposed Washtrays was validated according to the FDA guidance document, *"Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling"*.

Non-clinical testing data submitted, referenced, or relied upon, including acceptance criteria and set specifications in test methodology and standards, are summarized in Table 5.7.1.

Table 5.7.1-Summary of Non-Clinical Testing of the Proposed Washtrays

Test Name	Test Methodology	Purpose	Acceptance Criteria	Results
Sterilization Cycle Validation	• ANSI/AAMI/ISO 17665-1:2006/ (R)2013 • ISO 17665-2:2009	To validate that the trays can be sterilized via moist-heat sterilization as specified on labeling (132° C for 4 minutes)	Sterility assurance level (SAL) of $\leq 10^{-6}$	Pass
Drying Validation	• AAMI TIR12: 2020 • ANSI/AAMI/ISO 17665-2:2009	To validate that the trays can be dried as specified on labeling (drying time of 20 minutes)	No visible moisture ≤ 3% weight gain of packaging and absorbable materials	Pass
Cleaning (Manual Pre-Cleaning and Automated Cleaning)	• AAMI TIR12:2020 • AMI ST98:2022 • ISO 17664	To validate that the trays can be cleaned as specified on labeling	No visible soil. Protein < 6.4 µg/cm^2 Hemoglobin <2.2 µg/cm^2	Pass
Reprocessing of Trays (cleaning and sterilization)	Internal Test Method	To confirm that the trays can be reprocessed as specified on labeling (up to 200 reprocessing cycles without any signs of abrasion)	No signs of flush rust, rust corrosion, deformation or damage	Pass
Simulated Use of Trays	Internal Test Method	To confirm that the trays can withstand simulated use of up to 500 repeated reposition cycles	No significant wear of the holders	Pass
Transportation Testing	• ASTM D 4728-06 • DIN EN ISO 60068-2-27 • ISTA 3A (2010)	To confirm that the instrument holder provides adequate fixing of the instruments during transportation	No visible damages Instruments fixed inside the Washtray and instrument holders	Pass
Load Test Handle	Internal Test Method	To confirm that no permanent deformation of the handle or the lid will occur	No permanent deformation of the handle or the lid with a load of 40N	Pass
Cytotoxicity	ISO 10993-5:2009	To confirm that no cytotoxic substances are released after reprocessing of the trays	Inhibition of cell proliferation must be at or below 30% compared to untreated cultures	Pass

The non-clinical testing confirms that the proposed Washtrays can be sterilized via moist-heat sterilization as specified on the labeling (132° C for 4 minutes) to a sterility assurance level (SAL) of $\leq 10^{-6}$. In addition, the dry time as specified on the labeling (20 min) was validated to confirm that there is no visible moisture and that the weight gain of packaging and absorbable materials is ≤ 3%. Testing met the acceptance criteria.

A study for the evaluation of the automated cleaning procedure by determination of protein and hemoglobin residues was performed. Simulated use cycles were performed for the tested devices prior to the cleaning validation. The limit value for residual protein content of 6.4 µg/cm^2 and hemoglobin content of 2.2 µg/ cm^2 was not exceeded.

The *in vitro* cytotoxicity test conducted confirms that no cytotoxic substances are released after reprocessing of the trays. The result shows that the acceptance criteria were not exceeded. The proposed Washtrays are biocompatible for their intended use.

Product use and wear were evaluated through simulated use testing on the proposed Washtrays. After 200 cycles of cleaning and sterilization, the Washtrays did not show any signs of damage or alterations due to reprocessing. All relevant markings were still visible or readable with the naked eye. In addition, the reprocessed Washtrays have been used to simulate repeated repositioning of relevant instruments. Five hundred (500) repeated positionings have been simulated for each holder. The retention force of the holders was measured before and after the 500 repeated positionings were conducted. All tested Washtray instrument holders passed the repeated repositioning test and initial and final pull-off test to determine the retention force. There were no signs of damage or alterations after testing, and the instruments were safely seated in the holders.

The proposed Washtrays were evaluated for their ability to withstand vertical stresses during short-distance transportation. Tests were performed with a loaded tray to evaluate if the instrument holders provide adequate fixing of the instruments. The Washtrays passed the vertical vibration and respective shock stresses.

The handle of the proposed Washtrays was tested for its suitability in terms of load capacity. The handle was pulled vertically and did not result in permanent deformation of the handle or the lid. The acceptance criterion was achieved. The handle is sufficiently resilient.
For all conducted test it can be shown that the acceptance criteria were met. The non-clinical test data support the conclusion that the proposed Washtrays are safe, effective and perform as intended.

5.8 Conclusion

The conclusions drawn from the non-clinical tests demonstrate that the proposed device is as safe, as effective, and performs as well as or better than the predicate device K212932.