



U.S. Department of Health & Human Services

Food and Drug Administration

SAVE REQUEST

USER: (mac)
FOLDER: K103244 - 251 pages
COMPANY: DENTSPLY INTL., INC. (DENTSPLYD)
PRODUCT: CLEANSER, ROOT CANAL (KJJ)
SUMMARY: Product: QMIX 2IN1 ENDODONTIC IRRIGATING SOLUTION

DATE REQUESTED: Sep 26, 2012

DATE PRINTED: Sep 26, 2012

Note: Printed



FEB 14 2011

K103244

DENTSPLY

SECTION 5. 510(k) SUMMARY

for

QMix™ 2in1 Endodontic Irrigating Solution

DENTSPLY International

World Headquarters
Susquehanna Commerce Center
221 West Philadelphia Street
York, PA 17405-0872
(717) 845-7511 (voice)
(717) 849-4343 (fax)
www.dentsply.com

1. Submitter Information:

DENTSPLY International
Susquehanna Commerce Center
221 West Philadelphia Street
York, PA 17405

Contact Person: Helen Lewis
Telephone Number: 717-849-4229
Fax Number: 717-849-4343

Date Prepared: 01 February 2011

2. Device Name:

- Proprietary Name: QMix™ 2in1 Endodontic Irrigating Solution
- Classification Name: Cleanser, Root Canal
- CFR Number: N/A
- Device Class: Unclassified
- Product Code: KJJ

3. Predicate Device:

BioPure MTAD Root Canal Cleanser, DENTSPLY International, K053167

4. Description of Device:

QMix™ 2in1 Endodontic Irrigating Solution is a premixed dual-action device that cleanses and disinfects the root canal system by removing the smear layer and killing bacteria after endodontic instrumentation.

5. Indications for Use:

QMix™ 2in1 Endodontic Irrigating Solution is a premixed dual-action device that cleanses and disinfects the root canal system after endodontic instrumentation.

6. Description of Safety and Substantial Equivalence:
Technological Characteristics.

All of the components found in QMix™ 2in1 Endodontic Irrigating Solution have been used in legally marketed devices and were found safe for dental use. We believe that prior use of components in legally marketed devices, the performance and biocompatibility data provided support the safety and effectiveness of QMix™ 2in1 Endodontic Irrigating Solution for the indicated uses.

Non-Clinical Performance Data.

The efficacy and biocompatibility of QMix™ 2in1 Endodontic Irrigating Solution was demonstrated *via* non-clinical *in vitro* and *ex vivo* studies.

Clinical Performance Data.

No clinical studies were conducted on this device.

Conclusion as to Substantial Equivalence

QMix™ 2in1 Endodontic Irrigating Solution, to be manufactured by DENTSPLY International, is substantially equivalent to the currently cleared and marketed BioPure MTAD root canal cleanser.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room -WO66-G609
Silver Spring, MD 20993-0002

Ms. Helen Lewis
Director of Corporate Compliance and Regulatory Affairs
DENTSPLY International
Susquehanna Commerce Center
221 West Philadelphia Street
York, Pennsylvania 17405

FEB 14 2011

Re: K103244
Trade/Device Name: QMix™ 2in1 Endodontic Irrigating Solution
Regulatory Class: Unclassified
Product Code: KJJ
Dated: February 1, 2011
Received: February 2, 2011

Dear Ms. Lewis:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION 4. INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K103244

Device Name: QMix™ 2in1 Endodontic Irrigating Solution

Indications for Use:

QMix™ 2in1 Endodontic Irrigating Solution is a premixed dual-action device that cleanses and disinfects the root canal system after endodontic instrumentation.

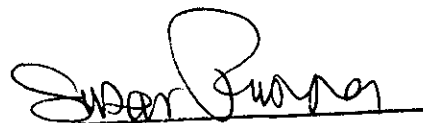
Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE—CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)

Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K103244



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room --WO66-G609
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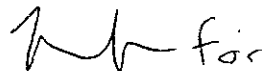
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Sincerely yours,



Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

0002

SECTION 4. INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K103244

Device Name: QMix™ 2in1 Endodontic Irrigating Solution

Indications for Use:

QMix™ 2in1 Endodontic Irrigating Solution is a premixed dual-action device that cleanses and disinfects the root canal system after endodontic instrumentation.


Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE—CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K103244

0003



U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center 6 WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

January 20, 2011

DENTSPLY INTL., INC.

SUSQUEHANNA COMMERCE CENTER 221 W PHILADELPHIA ST. STE 60

YORK, PENNSYLVANIA 17404

UNITED STATES

ATTN: HELEN LEWIS

510k Number: K103244

Product: QMIX 2IN1 ENDODONTIC IRRIGATING

We are holding your above-referenced Premarket Notification (510(k)) for 30 days pending receipt of the additional information that was requested by the Office of Device Evaluation. Please remember that all correspondence concerning your submission MUST cite your 510(k) number and be sent in duplicate to the Document Mail Center at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at

<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm>.

The deficiencies identified represent the issues that we believe need to be resolved before our review of your 510(k) submission can be successfully completed. In developing the deficiencies, we carefully considered the statutory criteria as defined in Section 513(i) of the Federal Food, Drug, and Cosmetic Act for determining substantial equivalence of your device. We also considered the burden that may be incurred in your attempt to respond to the deficiencies. We believe that we have considered the least burdensome approach to resolving these issues. If, however, you believe that information is being requested that is not relevant to the regulatory decision or that there is a less burdensome way to resolve the issues, you should follow the procedures outlined in the "A Suggested Approach to Resolving Least Burdensome Issues" document. It is available on our Center web page at: <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceProvisionsofFDAModernizationAct/ucm136685.htm>.

If after 30 days the additional information (AI), or a request for an extension of time, is not received, we will discontinue review of your submission and proceed to delete your file from our review system (21 CFR 807.87(l)). Please note our guidance document entitled, "Guidance for Industry and FDA Staff, FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment". If the submitter does submit a written request for an extension, FDA will permit the 510(k) to remain on hold for up to a maximum of 180 days from the date of the AI request. The purpose of this document is to assist agency staff and the device industry in understanding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee and Modernization Act. You may review this document at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089735.htm>. Pursuant to 21 CFR 20.29, a copy of your 510(k) submission will remain in the Office of Device Evaluation. If you then wish to resubmit this 510(k) notification, a new number will be assigned and your submission will be considered a new premarket notification submission.

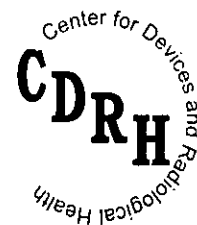
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Please remember that the Safe Medical Devices Act of 1990 states that you may not place this device into commercial distribution until you receive a decision letter from FDA allowing you to do so.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301)796-7100 or at their toll-free number (800)638-2041, or contact the 510k staff at (301)796-5640.

Sincerely yours,

Marjorie Shulman
Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and Radiological Health



To: The Record

From: Biologist, DEDB, DAGID, ODE, CDRH

Subject: K103244

Date: January 19, 2011

Background

Dentsply, International submitted a 510(k) for QMix 2 in 1 Irrigating Solution used to clean and disinfect the root canal following endodontic instrumentation. I spoke to Helen Lewis of Dentsply to request the following additional information:

1. Remove the statement "killing bacterial" from the indication for use statement.
2. Explain why the company is (b)(4) in this device.
3. Describe the mode of action, comparing it to the predicate.
4. Describe the cytotoxicity data included in the document.

I explained to Ms. Lewis that I will be placing this document on telephone hold until it is submitted to the document mail center.

Recommendation

Place document on telephone hold.

Myra E. Browne

0022

1/19/11



U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center 6 WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

November 04, 2010

DENTSPLY INTL., INC.

SUSQUEHANNA COMMERCE CENTER 221 W PHILADELPHIA ST. STE 60

YORK, PENNSYLVANIA 17404

UNITED STATES

ATTN: HELEN LEWIS

510k Number: K103244

Received: 11/2/2010

Product: QMIX 2IN1 ENDODONTIC IRRIGATING

The Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH), has received the Premarket Notification, (510(k)), you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act (Act) for the above referenced product and for the above referenced 510(k) submitter. Please note, if the 510(k) submitter is incorrect, please notify the 510(k) Staff immediately. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in all future correspondence that relates to this submission. We will notify you when the processing of your 510(k) has been completed or if any additional information is required. **YOU MAY NOT PLACE THIS DEVICE INTO COMMERCIAL DISTRIBUTION UNTIL YOU RECEIVE A LETTER FROM FDA ALLOWING YOU TO DO SO.**

Please remember that all correspondence concerning your submission **MUST** be sent to the Document Mail Center (DMC) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official 510(k) submission.

On September 27, 2007, the President signed an act reauthorizing medical device user fees for fiscal years 2008 - 2012. The legislation - the Medical Device User Fee Amendments of 2007 is part of a larger bill, the Food and Drug Amendments Act of 2007. Please visit our website at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceUserFeeandModernizationActMDUFMA/default.htm>

for more information regarding fees and FDA review goals. In addition, effective January 2, 2008, any firm that chooses to use a standard in the review of ANY new 510(k) needs to fill out the new standards form (Form 3654) and submit it with their 510(k). The form may be found at <http://www.fda.gov/AboutFDA/ReportsManualsForms/Forms/default.htm>.

We remind you that Title VIII of the Food and Drug Administration Amendments Act of 2007 (FDAAA) amended the PHS Act by adding new section 402(j) (42 U.S.C. § 282(j)), which expanded the current database known as ClinicalTrials.gov to include mandatory registration and reporting of results for applicable clinical trials of human drugs (including biological products) and devices. Section 402(j) requires that a certification form <http://www.fda.gov/AboutFDA/ReportsManualsForms/Forms/default.htm> accompany 510(k)/HDE/PMA submissions. The agency has issued a draft guidance titled: "Certifications To Accompany Drug, Biological

0024

Product, and Device Applications/Submissions: Compliance with Section 402(j) of The Public Health Service Act, Added By Title VIII of The Food and Drug Administration Amendments Act of 2007”
<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm134034.htm>. According to the draft guidance, 510(k) submissions that do not contain clinical data do not need the certification form.

Please note the following documents as they relate to 510(k) review: 1) Guidance for Industry and FDA Staff entitled, “Interactive Review for Medical Device Submissions: 510(k)s, Original PMAs, PMA Supplements, Original BLAs and BLA Supplements”. This guidance can be found at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm>. Please refer to this guidance for information on a formalized interactive review process. 2) Guidance for Industry and FDA Staff entitled, “Format for Traditional and Abbreviated 510(k)s”. This guidance can be found at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm>. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

In all future premarket submissions, we encourage you to provide an electronic copy of your submission. By doing so, you will save FDA resources and may help reviewers navigate through longer documents more easily. Under CDRH's e-Copy Program, you may replace one paper copy of any premarket submission (e.g., 510(k), IDE, PMA, HDE) with an electronic copy. For more information about the program, including the formatting requirements, please visit our web site at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/ucm134508.html>. In addition, the 510(k) Program Video is now available for viewing on line at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm070201.htm>.

Please ensure that whether you submit a 510(k) Summary as per 21 CFR 807.92, or a 510(k) Statement as per 21 CFR 807.93, it meets the content and format regulatory requirements.

Lastly, you should be familiar with the regulatory requirements for medical devices available at Device Advice <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm>. If you have questions on the status of your submission, please contact DSMICA at (301)796-7100 or the toll-free number (800)638-2041, or at their internet address <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm>. If you have procedural questions, please contact the 510(k) Staff at (301)796-5640.

Sincerely,

510(k) Staff

0025

ORIGINAL

PREMARKET NOTIFICATION

QMix™ 2in1 Irrigating Solution

DENTSPLY INTERNATIONAL

November 1, 2010

K14

0026

TABLE OF CONTENTS

1. MDUFMA Cover Sheet	1	
2. CDRH Premarket Review Submission Cover Sheet.....	2	
3. 510(k) Cover Letter.....	7	
4. Indications for Use Statement	8	
5. 510(k) Summary.....	9	
6. Truthful and Accuracy Statement	11	
7. Class III Summary and Certification.....	12	<input checked="" type="checkbox"/> NA
8. Financial Certification or Disclosure Statements.....	12	<input checked="" type="checkbox"/> NA
9. Declarations of Conformity and Summary Reports.....	12	<input checked="" type="checkbox"/> NA
10. Executive Summary	13	
11. Device Description	16	
12. Substantial Equivalence Discussion.....	18	
13. Proposed Labeling.....	21	
14. Sterilization and Shelf Life	26	<input type="checkbox"/> NA
15. Biocompatibility	27	<input type="checkbox"/> NA
16. Software	28	<input checked="" type="checkbox"/> NA
17. Electromagnetic Compatibility and Electrical Safety	28	<input checked="" type="checkbox"/> NA
18. Performance Testing – Bench	29	<input type="checkbox"/> NA
19. Performance Testing – Animal	31	<input checked="" type="checkbox"/> NA
20. Performance Testing – Clinical.....	31	<input checked="" type="checkbox"/> NA
21. Certification of Compliance Requirements of ClinicalTrials.gov	32	
22. Standards Data Report for 510(k)s.....	33	<input type="checkbox"/> NA
Appendix A.....	40	
Appendix B	53	
Appendix C	98	
Appendix D	154	
Appendix E.....	177	
Appendix F	198	

0027

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION MEDICAL DEVICE USER FEE COVER SHEET		PAYMENT IDENTIFICATION NUMBER: MD6051697-956733 Write the Payment Identification number on your check.			
A completed cover sheet must accompany each original application or supplement subject to fees. If payment is sent by U.S. mail or courier, please include a copy of this completed form with payment. Payment and mailing instructions can be found at: http://www.fda.gov/oc/mdufma/cover sheet.html					
1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code) DENTSPLY INTERNATIONAL 221 West Philadelphia Street Suite 60 York PA 17404 US 1.1 EMPLOYER IDENTIFICATION NUMBER (EIN) *****4669		2. CONTACT NAME Rebecca Sporer 2.1 E-MAIL ADDRESS rsporer@dentsply.com 2.2 TELEPHONE NUMBER (include Area code) 717-849 4793 2.3 FACSIMILE (FAX) NUMBER (Include Area code) 717-849			
3. TYPE OF PREMARKET APPLICATION (Select one of the following in each column; if you are unsure, please refer to the application descriptions at the following web site: http://www.fda.gov/oc/mdufma) <table border="0"> <tr> <td> Select an application type: <input checked="" type="checkbox"/> Premarket notification(510(k)); except for third party <input type="checkbox"/> 513(g) Request for Information <input type="checkbox"/> Biologics License Application (BLA) <input type="checkbox"/> Premarket Approval Application (PMA) <input type="checkbox"/> Modular PMA <input type="checkbox"/> Product Development Protocol (PDP) <input type="checkbox"/> Premarket Report (PMR) <input type="checkbox"/> Annual Fee for Periodic Reporting (APR) <input type="checkbox"/> 30-Day Notice </td> <td> 3.1 Select a center <input checked="" type="checkbox"/> CDRH <input type="checkbox"/> CBER 3.2 Select one of the types below <input checked="" type="checkbox"/> Original Application <u>Supplement Types:</u> <input type="checkbox"/> Efficacy (BLA) <input type="checkbox"/> Panel Track (PMA, PMR, PDP) <input type="checkbox"/> Real-Time (PMA, PMR, PDP) <input type="checkbox"/> 180-day (PMA, PMR, PDP) </td> </tr> </table>				Select an application type: <input checked="" type="checkbox"/> Premarket notification(510(k)); except for third party <input type="checkbox"/> 513(g) Request for Information <input type="checkbox"/> Biologics License Application (BLA) <input type="checkbox"/> Premarket Approval Application (PMA) <input type="checkbox"/> Modular PMA <input type="checkbox"/> Product Development Protocol (PDP) <input type="checkbox"/> Premarket Report (PMR) <input type="checkbox"/> Annual Fee for Periodic Reporting (APR) <input type="checkbox"/> 30-Day Notice	3.1 Select a center <input checked="" type="checkbox"/> CDRH <input type="checkbox"/> CBER 3.2 Select one of the types below <input checked="" type="checkbox"/> Original Application <u>Supplement Types:</u> <input type="checkbox"/> Efficacy (BLA) <input type="checkbox"/> Panel Track (PMA, PMR, PDP) <input type="checkbox"/> Real-Time (PMA, PMR, PDP) <input type="checkbox"/> 180-day (PMA, PMR, PDP)
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4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status) <input type="checkbox"/> YES, I meet the small business criteria and have submitted the required qualifying documents to FDA <input checked="" type="checkbox"/> NO, I am not a small business 4.1 If Yes, please enter your Small Business Decision Number:					
5. FDA WILL NOT ACCEPT YOUR SUBMISSION IF YOUR COMPANY HAS NOT PAID AN ESTABLISHMENT REGISTRATION FEE THAT IS DUE TO FDA. HAS YOUR COMPANY PAID ALL ESTABLISHMENT REGISTRATION FEES THAT ARE DUE TO FDA? <input checked="" type="checkbox"/> YES (All of our establishments have registered and paid the fee, or this is our first device, and we will register and pay the fee within 30 days of FDA's approval/clearance of this device.) <input type="checkbox"/> NO (If "NO," FDA will not accept your submission until you have paid all fees due to FDA. This submission will not be processed; see http://www.fda.gov/cdrh/mdufma for additional information)					
6. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION. <table border="0"> <tr> <td> <input type="checkbox"/> This application is the first PMA submitted by a qualified small business, including any affiliates <input type="checkbox"/> This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only </td> <td> <input type="checkbox"/> The sole purpose of the application is to support conditions of use for a pediatric population <input type="checkbox"/> The application is submitted by a state or federal government entity for a device that is not to be distributed commercially </td> </tr> </table>				<input type="checkbox"/> This application is the first PMA submitted by a qualified small business, including any affiliates <input type="checkbox"/> This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only	<input type="checkbox"/> The sole purpose of the application is to support conditions of use for a pediatric population <input type="checkbox"/> The application is submitted by a state or federal government entity for a device that is not to be distributed commercially
<input type="checkbox"/> This application is the first PMA submitted by a qualified small business, including any affiliates <input type="checkbox"/> This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only	<input type="checkbox"/> The sole purpose of the application is to support conditions of use for a pediatric population <input type="checkbox"/> The application is submitted by a state or federal government entity for a device that is not to be distributed commercially				
7. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION OF USE FOR ANY ADULT POPULATION? (If so, the application is subject to the fee that applies for an original premarket approval application (PMA)). <input type="checkbox"/> YES <input checked="" type="checkbox"/> NO					
8. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION \$4,348.00 20-Sep-2010					

Form FDA 3601 (01/2007)

["Close Window"](#) [Print Cover sheet](#)

0028 000001

SECTION 2. CDRH PREMARKET REVIEW SUBMISSION COVER SHEET (FORM FDA 3514)

Date of Submission November 1, 2010	User Fee Payment ID Number (see attached MDUFMA cover sheet)	FDA Submission Document Number (if known)
--	---	---

SECTION A TYPE OF SUBMISSION

PMA <input type="checkbox"/> Original Submission <input type="checkbox"/> Premarket Report <input type="checkbox"/> Modular Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Report <input type="checkbox"/> Report Amendment <input type="checkbox"/> Licensing Agreement	PMA & HDE Supplement <input type="checkbox"/> Regular (180 day) <input type="checkbox"/> Special <input type="checkbox"/> Panel Track (PMA Only) <input type="checkbox"/> 30-day Supplement <input type="checkbox"/> 30-day Notice <input type="checkbox"/> 135-day Supplement <input type="checkbox"/> Real-time Review <input type="checkbox"/> Amendment to Suppl.	PDP <input type="checkbox"/> Original PDP <input type="checkbox"/> Notice of Completion <input type="checkbox"/> Amendment to PDP	510(k) <input checked="" type="checkbox"/> Original Submission: <input checked="" type="checkbox"/> Traditional <input type="checkbox"/> Special <input type="checkbox"/> Abbreviated (Complete section I, Page 5) <input type="checkbox"/> Additional Information <input type="checkbox"/> Third Party	Meeting <input type="checkbox"/> Pre-510(k) Meeting <input type="checkbox"/> Pre-IDE Meeting <input type="checkbox"/> Pre-PMA Meeting <input type="checkbox"/> Pre-PDP Meeting <input type="checkbox"/> Day 100 Meeting <input type="checkbox"/> Agreement Meeting <input type="checkbox"/> Determination Meeting <input type="checkbox"/> Other (specify):
IDE <input type="checkbox"/> Original Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement	Humanitarian Device Exemption (HDE) <input type="checkbox"/> Original Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement <input type="checkbox"/> Report <input type="checkbox"/> Report Amendment	Class II Exemption Petition <input type="checkbox"/> Original Submission <input type="checkbox"/> Additional Information	Evaluation of Automatic Class III Designation (De Novo) <input type="checkbox"/> Original Submission <input type="checkbox"/> Additional Information	Other Submission <input type="checkbox"/> 513(g) <input type="checkbox"/> Other (describe submission):

Have you used or cited Standards in your submission? ☒ Yes ☐ No (If Yes, please complete Section I, Page 5)

SECTION B SUBMITTER, APPLICANT OR SPONSOR

Company / Institution Name DENTSPLY International, Inc.		Establishment Registration Number (if known) 2511302 (Owner/Operator)	
Street Address Susquehanna Commerce Ctr., 221 W. Philadelphia St., Suite 60		Phone Number (including area code) (717) 845-7511 ext 54229	
York		FAX Number (including area code) (717) 849-4343	
State / Province PA	ZIP/Postal Code 17404	Country USA	
Contact Name Helen Lewis			
Contact Title Director of Corporate Compliance & Regulatory Affairs		Contact E-mail Address hlewis@dentsply.com	

SECTION C APPLICATION CORRESPONDENT (e.g., consultant, if different from above)

Company / Institution Name			
Street Address		Phone Number (including area code) ()	
City		FAX Number (including area code) ()	
State / Province	ZIP/Postal Code	Country	
Contact Name			
Contact Title		Contact E-mail Address	

SECTION D1

REASON FOR APPLICATION - PMA, PDP, OR HDE

- ☒ Withdrawal
☐ Additional or Expanded Indications
☐ Request for Extension
☐ Post-approval Study Protocol
☐ Request for Applicant Hold
☐ Request for Removal of Applicant Hold
☐ Request to Remove or Add Manufacturing Site

- ☐ Change in design, component, or specification:
☐ Software / Hardware
☐ Color Additive
☐ Material
☐ Specifications
☐ Other (specify below)

- ☐ Location change:
☐ Manufacturer
☐ Sterilizer
☐ Packager

Other (specify below)

- ☐ Process change:
☐ Manufacturing
☐ Sterilization
☐ Packaging
☐ Other (specify below)

- ☐ Labeling change:
☐ Indications
☐ Instructions
☐ Performance
☐ Shelf Life
☐ Trade Name
☐ Other (specify below)

- ☐ Report Submission:
☐ Annual or Periodic
☐ Post-approval Study
☐ Adverse Reaction
☐ Device Defect
☐ Amendment

- ☐ Response to FDA correspondence:

- ☐ Change in Ownership
☐ Change in Correspondent
☐ Change of Applicant Address

- ☐ Other Reason (specify):

SECTION D2

REASON FOR APPLICATION - IDE

- ☐ New Device
☐ New Indication
☐ Addition of Institution
☐ Expansion / Extension of Study
☐ IRB Certification
☐ Termination of Study
☐ Withdrawal of Application
☐ Unanticipated Adverse Effect
☐ Notification of Emergency Use
☐ Compassionate Use Request
☐ Treatment IDE
☐ Continued Access
☐ Request for Removal of Applicant Hold

- ☐ Change in:
☐ Correspondent / Applicant
☐ Design / Device
☐ Informed Consent
☐ Manufacturer
☐ Manufacturing Process
☐ Protocol - Feasibility
☐ Protocol - Other
☐ Sponsor

- ☐ Report submission:
☐ Current Investigator
☐ Annual Progress Report
☐ Site Waiver Report
☐ Final

- ☐ Repose to FDA Letter Concerning:
☐ Conditional Approval
☐ Deemed Approved
☐ Deficient Final Report
☐ Deficient Progress Report
☐ Deficient Investigator Report
☐ Disapproval
☒ Request Extension of Time to Respond to FDA
☐ Request Meeting
☐ Request Hearing
 Manufacturer

- ☐ Other Reason (specify):

SECTION D3

REASON FOR SUBMISSION - 510(k)

- ☒ New Device

- ☐ Additional or Expanded Indications

- ☐ Change in Technology

- ☐ Other Reason (specify):

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SECTION E ADDITIONAL INFORMATION ON 510(k) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed

1	KJJ	2		3		4	
5		6		7		8	

Summary of, or statement concerning, safety and effectiveness information

☒ 510 (k) summary attached
510 (k) statement

Information on devices to which substantial equivalence is claimed (if known)

510(k) Number	Trade or Proprietary or Model Name	Manufacturer
1 K053167	1 BioPure MTAD	1 DENTSPLY Tulsa Dental Specialties
2	2	2
3	3	3
4	4	4
5	5	5
6	6	6

SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification

Cleanser, Root Canal

Trade or Proprietary or Model Name for This Device	Model Number
1 QMix™ 2in1 Endodontic Irrigating Solution	1
	2
3	3
4	4
5	5

FDA document numbers of all prior related submissions (regardless of outcome)

1	2	3	4	5	6
7	8	9	10	11	12

Data Included in Submission

☒ Laboratory Testing ☐ Animal Trials ☐ Human Trials

SECTION G PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS

Product Code KJJ	C.F.R. Section (if applicable) Unknown	Device Class <input type="checkbox"/> Class I <input type="checkbox"/> Class II <input type="checkbox"/> Class III <input checked="" type="checkbox"/> Unclassified
Classification Panel Dental		

Indications (from labeling)

QMix™ 2in1 Irrigating Solution is a premixed dual-action device that cleanses and disinfects the root canal system by removing the smear layer and killing bacteria after endodontic instrumentation.

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Note: Submission of this information does not affect the need to submit a 2891 or 2891a Device Establishment Registration form.

FDA Document Number (if known)

SECTION H MANUFACTURING / PACKAGING / STERILIZATION SITES RELATING TO A SUBMISSION

<input checked="" type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete	FDA Establishment Registration Number 2515379	<input type="checkbox"/> Manufacturer <input checked="" type="checkbox"/> Contract Manufacturer	<input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Repackager / Relabeler
Company / Institution Name DENTSPLY International		Establishment Registration Number 2511302	
Division Name (if applicable) DENTSPLY Caulk		Phone Number (including area code) (717) 849-4229	
Street Address 38 West Clark Avenue		FAX Number (including area code) (717) 849-4343	
City Milford		State / Province DE	ZIP/Postal Code 19963
Country USA			
Contact Name Helen Lewis	Contact Title Director, Corporate Compliance & Regulatory Affairs	Contact E-mail Address hlewis@dentsply.com	

<input type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete	FDA Establishment Registration Number	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Manufacturer	<input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Repackager / Relabeler
Company / Institution Name		Establishment Registration Number	
Division Name (if applicable)		Phone Number (including area code) ()	
Street Address		FAX Number (including area code) ()	
City		State / Province	ZIP/Postal Code
Country			
Contact Name	Contact Title	Contact E-mail Address	

<input type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete	FDA Establishment Registration Number	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Manufacturer	<input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Repackager / Relabeler
Company / Institution Name		Establishment Registration Number	
Division Name (if applicable)		Phone Number (including area code) ()	
Street Address		FAX Number (including area code) ()	
City		State / Province	ZIP/Postal Code
Country			
Contact Name	Contact Title	Contact E-mail Address	

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SECTION I UTILIZATION OF STANDARDS

Note: Complete this section if your application or submission cites standards or includes a "Declaration of Conformity to a Recognized Standard" statement.

	Standards No.	Standards Organization	Standards Title	Version	Date
1	ISO-10993-10	ISO	Biological evaluation of medical devices-Part 10: Tests for irritation and sensitization	2	10-1-2002/(R) 2008
2	ISO 10993-5	ISO	Biological evaluation of medical devices-- Part 5: Tests for cytotoxicity: in vitro methods 2009	4	10-13-2009
3	ISO 10993-10	ISO	Biological evaluation of medical devices-Part 10: Tests for irritation and sensitization 2010	3	08/01/2010
4					
5					
6					
7					

Please include any additional standards to be cited on a separate page.

Public reporting burden for this collection of information is estimated to average 0.5 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Food and Drug Administration
CDRH (HFZ-342)
9200 Corporate Blvd.
Rockville, MD 20850

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control

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November 1, 2010

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

FDA CDRH DMC
NOV 2 2010
Received

DENTSPLY International
World Headquarters
Susquehanna Commerce Center
221 West Philadelphia Street
York, PA 17405-0872
(800) 877-0020
Fax (717) 849-4343
www.dentsply.com

TRADITIONAL 510(k) NOTIFICATION: QMix™ 2in1 Irrigating Solution

DENTSPLY International intends to market a new dual-action endodontic irrigation solution that is intended to cleanse and disinfect the root canal system by killing bacteria and removing smear layer after endodontic instrumentation.

Classification Name	Cleanser, Root Canal
FDA CDRH Panel	Dental
Product Code	KJJ
Regulation Number	None
Class #	Unclassified

DENTSPLY International will take appropriate action to comply with consensus standards for Root Canal Cleanser if and when applicable.

The QMix™ 2in1 Irrigating Solution is substantially equivalent to DENTSPLY International, BioPure MTAD, K053167, with an FDA clearance date of December 8th, 2005 and product code KJJ.

We request that the FDA keep all trade secret information permanently confidential. We hereby certify that we understand and comply with or will comply with the regulations set forth in 21 CFR 807.95(b)(1)(i-v).

Sincerely,

Helen Lewis
Director of Corporate Compliance and Regulatory Affairs
(717) 845-7511 (x54229)

Enclosures

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SECTION 4. INDICATIONS FOR USE STATEMENT

510(k) Number (if known): _____

Device Name: QMix™ 2in1 Irrigating Solution

Indications for Use:

QMix™ 2in1 Irrigating Solution is a premixed dual-action device that cleanses and disinfects the root canal system by removing the smear layer and killing bacteria after endodontic instrumentation.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE—CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



SECTION 5. 510(k) SUMMARY
for
QMix™ 2in1 Irrigating Solution

DENTSPLY International
World Headquarters
Susquehanna Commerce Center
221 West Philadelphia Street
York, PA 17405-0872
(800) 877-0020
Fax (717) 849-4343
www.dentsply.com

1. Submitter Information:

DENTSPLY International
Susquehanna Commerce Center
221 West Philadelphia Street
York, PA 17405

Contact Person: Helen Lewis
Telephone Number: 717-849-4229
Fax Number: 717-849-4343

Date Prepared: November 1, 2010

2. Device Name:

- Proprietary Name: QMix™ 2in1 Irrigating Solution
- Classification Name: Cleanser, Root Canal
- CFR Number: N/A
- Device Class: Unclassified
- Product Code: KJJ

3. Predicate Device:

BioPure MTAD Root Canal Cleanser, DENTSPLY International, K053167

4. Description of Device:

QMix™ 2in1 Irrigating Solution is a premixed dual-action device that cleanses and disinfects the root canal system by removing the smear layer and killing bacteria after endodontic instrumentation.

5. Indications for Use:

QMix™ 2in1 Irrigating Solution is a premixed dual-action device that cleanses and disinfects the root canal system by removing smear layer and killing bacteria after endodontic instrumentation.

6. Description of Safety and Substantial Equivalence:

Technological Characteristics.

All of the components found in QMix™ 2in1 Irrigating Solution have been used in legally marketed devices and were found safe for dental use. We believe that prior use of components in legally marketed devices, the performance and biocompatibility data provided support the safety and effectiveness of QMix™ 2in1 Irrigating Solution for the indicated uses.

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Non-Clinical Performance Data.

The efficacy and biocompatibility of QMix™ 2in1 Irrigating Solution was demonstrated *via* non-clinical *in vitro* and *ex vivo* studies.

Clinical Performance Data.

No clinical studies were conducted on this device.

Conclusion as to Substantial Equivalence

QMix™ 2in1 Irrigating Solution, to be manufactured by DENTSPLY International, is substantially equivalent to the currently cleared and marketed BioPure MTAD root canal cleanser.

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SECTION 6. TRUTHFUL AND ACCURACY STATEMENT

[As Required by 21 CFR 807.87(k)]

I certify that, in my capacity as Director of Corporate Compliance and Regulatory Affairs of DENTSPLY International, I believe to the best of my knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.



Helen Lewis
Director of Corporate Compliance and Regulatory Affairs

November 1, 2010

K_____ QMix™ 2in1 Irrigating Solution

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SECTION 7. CLASS III SUMMARY AND CERTIFICATION

☒ **This section is not applicable. Device is not a Class III.**

SECTION 8. FINANCIAL CERTIFICATION OR DISCLOSURE STATEMENT

☒ **This section is not applicable; this submission does not include clinical study data.**

SECTION 9. DECLARATIONS OF CONFORMITY AND SUMMARY REPORTS

☒ **This section is not applicable; recommended for an Abbreviated 510(k) submission.**

0039

SECTION 10. EXECUTIVE SUMMARY

Description of Device

QMix™ 2in1 Irrigating Solution is a premixed dual-action device that cleanses and disinfects the root canal system by removing the smear layer and killing bacteria after endodontic instrumentation. Details are found under DEVICE DESCRIPTION.

Similarities and Differences

QMix™ 2in1 Irrigating Solution is similar to BioPure MTAD in its capacity to chemically clean and disinfect the root canal system. As with BioPure MTAD, it contains effective antimicrobial and smear layer removing agents; unlike BioPure MTAD, these agents are not antibacterial or citric acid-based chemicals, respectively. Unlike BioPure MTAD, QMix is not acidic at the time of application.

Table 10.1 Device Comparison Table

Element	Predicate Device	New Device
510(k)	K053167	To be assigned
Device Name	BioPure MTAD Root Canal Cleanser	QMix™ 2in1 Irrigating Solution
Manufacturer	DENTSPLY International	SAME
Intended Use	Used to chemically clean the canal and disinfect the root canal system after endodontic instrumentation	Is a premixed dual-action device that cleanses and disinfects that root canal system by removing smear layer and killing bacteria after endodontic instrumentation.
Active Ingredient	(b)(4)	(b)(4)
Physical Properties	(b)(4) er (b)(4); Clear, colorless, odorless liquid (Citric Acid)	Clear, colorless, odorless liquid solution.
Chemical Properties	Acidic solution during use. (b)(4)	Slightly basic solution (b)(4)
Configurations/Dimensions	(b)(4) solution in 5ml Prefilled syringe; 5ml for single canal application, 20ml for multi- canal application.	(b)(4) containers.
Performance	Predicate Device	New Device
% bacterial kill (<i>in vitro</i>)	≥99.99%	SAME
Material Compatibility	Solution compatible with primary packaging.	SAME
Toxicological Properties	Biocompatible for intended use / duration	SAME
Shelf Life	2 years	SAME

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Summary of Performance Testing

1. Performance Testing – Bench

Bench testing was undertaken on this device to demonstrate its efficacy as a root canal cleanser. Specifically, the ability of the solution to remove smear layer from instrumented root canals and kill endodontic bacteria (eg. *Enterococcus faecalis*) using standard protocols developed by Nelson Labs (eg. kill time testing) or university dental research departments (smear layer removal).

Time Kill (*in vitro*)- Nelson Lab's: Document (b)(4) 01 (Appendix A)

Methodology: A measure (b)(4) was added to the test solution. A sample of the test solution was extracted into neutralizer medium after a set exposure time and assayed *via* plate count following incubation to determine the number of viable organisms remaining and therefore the percentage kill due to the test solution.

Results: Nelson Labs Report #519008 demonstrated that QMix™ 2in1 Irrigating Solution ("EBR 9210-999998-R210 R Exp 2011-02) demonstrated a greater than 99.99% reduction of the microorganism (*E. faecalis*) in 5 seconds. The negative control performed as anticipated with a kill rate of 6% in the same timeframe.

Conclusion: QMix™ 2in1 Irrigating Solution killed the test organism (*E. faecalis*) in five seconds by greater than 99.99%. This was superior to 2% Chlorhexidine with a 47% kill rate.

"The Effect of QMix on Removal of Canal Wall Smear Layer" (*ex vivo*) - Dr. Franklin Tay (Appendix B)

Methodology: (b)(4)

Results:

Conclusion:

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“Scanning Electron Microscopic Study of Intracanal Smear Layer Removal by a Novel Irrigant Solution” (ex vivo) (b)(4)

Methodology

Results:

Conclusion:

EDTA.

Performance Testing – Animal

☒ This section is not applicable

Performance Testing – Clinical

☒ This section is not applicable

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SECTION 11. DEVICE DESCRIPTION

QMix™ 2in1 Irrigating Solution is a premixed dual-action device that cleanses and disinfects the root canal system by removing smear layer and killing bacteria after endodontic instrumentation. The solution contains (b)(4)

QMix™ 2in1 Irrigating Solution is packaged in HDPE screw-capped containers fitted with tamper evidence seals. It is available in 5ml, 60ml and 480ml bulk-solution containers.

- The 5ml container will not be sold as a commercial product. It will be made available free-of-charge as a sample.
- The 60ml container will be fitted with a Luer Lock adaptor to enable the connection and direct dispensing of solution into a Luer Lock delivery syringe.
- The 480ml bulk-solution container will not be fitted with a Luer Lock adaptor.

Photographs and Engineering drawings are not applicable for a formulated product.

All of the components present in QMix™ 2in1 Irrigating Solution have been previously cleared for use as root canal cleansers, in concentrations higher than those present in QMix™ 2in1 Irrigating Solution. For this reason, the differences between the new and the predicate device do not affect safety and effectiveness.

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DEVICE DESCRIPTION (cont'd.)

Formulation Table – (Not being compared to predicate device)

TRADE SECRET - CONFIDENTIAL

Table 11.1 Formulation Table				
Component Name	Chemical Name	CAS#	Function	New Device
(b)(4)				
TOTAL				100.00

SECTION 12. SUBSTANTIAL EQUIVALENCE DISCUSSION

The QMix™ 2in1 Irrigating Solution is substantially equivalent to DENTSPLY International, BioPure MTAD, K053167, with an FDA clearance date of December 8th, 2005 and product code KJJ.

BioPure MTAD and QMix™ 2in1 Irrigating Solution are both designed to clean and disinfect the root canal system by combining the functions of smear layer removal and bacterial killing into a single step. This is done after initial irrigation of the root canal system with (b)(4), which

(b)(4) dissolves residual necrotic endodontic (pulpal) tissue and serves as the primary disinfection step and an antibacterial agent (Doxycycline Hydrate) in a solution containing a surfactant (Benzalkonium CO). QMix™ 2in1 Irrigating Solution is also used as a secondary (final) irrigation step, but does this in a shorter timeframe than BioPure MTAD. It uses an endodontic chelating/sequestering agent in place of citric acid (b)(4), and an antiseptic surfactant in place of a non-antiseptic surfactant.

SUBSTANTIAL EQUIVALENCE: (cont'd.)

Formulation Comparison Table – Device Components:

TRADE SECRET - CONFIDENTIAL

Table 12.1 Formulation Comparison Table						
Component Name	Chemical Name	CAS#	Function	Predicate	OMix™ 2in1	
(b)(4)						
TOTAL				100.00	100.00	

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SUBSTANTIAL EQUIVALENCE: (cont'd.)











Comparison of Performance Data / Physical Properties

Table 12.2 Comparison of Performance Data/Physical Properties			
Physical Property	Standard (ISO, ADA, ANSI, etc.)	Predicate Device	QMix™ 2in1 Irrigating Solution
Physical Appearance	N / A	Clear, pale yellow liquid (when components are mixed in preparation for use).	Clear, colorless liquid (requires no pre-mixing).

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SECTION 13. PROPOSED LABELING

DRAFT DEVICE LABEL

  IRRIGATING SOLUTION	<p>Manufactured for:</p> <p>DENTSPLY Tulsa Dental Specialties DENTSPLY International, Inc. 608 Rolling Hills Drive Johnson City, TN 37604 1-800-662-1202 1-800-597-2779 (fax) www.tulsadentalspecialties.com Made in U.S.A.</p> <p style="text-align: right;">Item: QMIX60ML</p>
<div style="display: flex; justify-content: space-around;"> <div style="text-align: center;">  CONSULT INSTRUCTIONS FOR USE </div> <div style="text-align: center;">  Rx Only For Dental Use Only </div> </div> <p>60 mL U.S. & Foreign Pats. Pend. 07/10</p>	<div style="display: flex; justify-content: space-around;"> <div style="text-align: center;">  NONRETURNABLE IF SEAL IS BROKEN </div> <div style="text-align: center;">  XXXXXX </div> <div style="text-align: center;">  LOT </div> <div style="text-align: center;">  XXXXXX </div> </div> <div style="display: flex; justify-content: space-around;">  +D716QMIX5ML01 </div> <div style="display: flex; justify-content: space-around;">  LOT/EXP DATE CODE </div>

<div style="display: flex; justify-content: space-around;"> <div style="text-align: center;">  XXXXXX EXP DATE </div> <div style="text-align: center;">  LOT XXXXXX </div> </div> <div style="display: flex; justify-content: space-around;">  +D716QMIX5ML01 </div> <div style="display: flex; justify-content: space-around;">  LOT/EXP DATE CODE </div>	<div style="display: flex; justify-content: space-between;"> <div style="width: 45%;">  <p>Manufactured for:</p> <p>DENTSPLY Tulsa Dental Specialties DENTSPLY International, Inc. 608 Rolling Hills Drive Johnson City, TN 37604 1-800-662-1202 1-800-597-2779 (fax) www.tulsadentalspecialties.com Made in U.S.A.</p> </div> <div style="width: 50%; text-align: center;">  IRRIGATING SOLUTION </div> </div> <div style="display: flex; justify-content: space-between; margin-top: 10px;"> <div style="width: 45%;">  CONSULT INSTRUCTIONS FOR USE </div> <div style="width: 50%; text-align: center;"> <p>Rx Only For Dental Use Only</p> <p>U. S. & Foreign Patent Pending. Item: QMIX5ML 5 ml Trial Size-Not For Resale 07/10 5 mL</p> </div> </div>
--	--

0048

DENTSPLY
TULSA DENTAL
SPECIALTIES



IRRIGATING SOLUTION

Manufactured for:

DENTSPLY Tulsa Dental Specialties

DENTSPLY International, Inc.

608 Rolling Hills Drive

Johnson City, TN 37604

1-800-662-1202

1-800-597-2779 (fax)

www.tulsadentalspecialties.com

BARCODE

BARCODE

Item: QMDX480ML U.S. & Foreign Pat. Pend. 571905 [R 09/10] 480 mL



NONRETURNABLE
IF SEAL IS BROKEN



CONSULT
INSTRUCTIONS
FOR USE



Keep Away From Sunlight Rx Only

Store At Room Temperature

LOT XXXXXXXXXXXXX



XXXXXXXXXX

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PROPOSED LABELING (cont'd)

DRAFT DIRECTIONS FOR USE (DFU)

DIRECTIONS FOR USE

DENTSPLY
TULSA DENTAL
SPECIALTIES

QMix™ 2in1
IRRIGATING SOLUTION

Manufactured for:
DENTSPLY Tulsa Dental Specialties
DENTSPLY International, Inc.
608 Rolling Hills Drive
Johnson City, TN 37604
1-800-662-1202
1-800-597-2779 (fax)
www.tulsadentalspecialties.com

Manufactured in U.S.A.

U.S. and foreign patents pending.



Keep Away From Sunlight Store At: Room Temperature



NON-RETURNABLE
IF SEAL IS BROKEN Rx Only

CAUTION:

- U.S. Federal law restricts the sale of this device to a dentist or clinician.

INDICATIONS FOR USE:

- QMix™ 2in1 Irrigating Solution is a premixed dual-action device that cleanses and disinfects the root canal system by removing smear layer and killing bacteria after endodontic instrumentation.

CONTRAINDICATIONS:

- Not for use as a general disinfectant and should not be used as such.
- Not for use as an oral rinse.

WARNINGS:

- Corrosive.
- Keep out of the reach of children.
- Use of this product, in a small number of patients, may cause difficulty breathing, swollen face or eyes, hives or rash. The patient should be advised to contact his/her dental professional immediately in the unlikely event that these symptoms occur.

- Skin contact may cause skin irritation. Symptoms include redness, itching, and pain. Immediately flush skin with plenty of cool soapy water for at least 15 minutes. Get medical attention.
- Avoid contact with eyes. Eye contact may cause severe eye irritation and abrasion. Immediately flush eyes with plenty of water for at least 15 minutes, lifting lower and upper eyelids occasionally. Get medical attention immediately.
- Direct inhalation may cause irritation to respiratory tract and mucous membranes. Symptoms may include coughing, shortness of breath. Remove patient to fresh air. If not breathing, give artificial respiration. If breathing is difficult, administer oxygen. Seek attention of a physician immediately.
- Ingestion may cause nausea, vomiting, diarrhea and difficulty in swallowing. If ingestion occurs, flush mouth with water and seek medical attention immediately. If person is conscious, induce vomiting. Never induce vomiting on an unconscious person.
- Use freshly opened packaged syringes and sterile irrigation needles. Do not reuse.
- Do not store QMix™ 2in1 in an application syringe.
- Use QMix™ 2in1 as indicated. Reducing the dosage will not achieve effective cleaning.

PRECAUTIONS:

- Store at room temperature. Keep out of direct sunlight. Do not refrigerate. Replace cap securely between uses.
- Use of up to 6.15% NaOCl for irrigation prior to use of QMix™ 2in1 is recommended.
- Rinse out the NaOCl with sterile water or saline prior to use of QMix™ 2in1.
- Use QMix™ 2in1 as indicated. Lower dosage (fewer milliliters) will not cleanse or disinfect the root canal as effectively.
- Use QMix™ 2in1 as the final irrigant before obturation.
- Do not use QMix™ 2in1 after expiration date.

PROPOSED LABELING (cont'd)

- Care should be taken not to cross-contaminate solution in bulk containers.
- Use in a well ventilated area.
- When handling this product, the use of eye/face protection, latex or non-latex gloves is recommended.
- Wash your hands following use. No eating, drinking or smoking while handling this product.
- Do not use this product if the tooth is not properly isolated with a dental dam and protective equipment.
- All root canal procedures should be performed with sufficient visibility.

ADVERSE REACTIONS:

- Use of this product, in a small number of patients, may cause difficulty breathing, swollen face or eyes, hives or rash. The patient should be advised to contact his/her dental professional immediately in the unlikely event that these symptoms occur.
- Skin contact may cause skin irritation. Symptoms include redness, itching, and pain. Immediately flush skin with plenty of cool soapy water for at least 15 minutes. Get medical attention.
- Avoid contact with eyes. Eye contact may cause severe eye irritation and abrasion. Immediately flush eyes with plenty of water for at least 15 minutes, lifting lower and upper eyelids occasionally. Get medical attention immediately.
- Direct inhalation may cause irritation to respiratory tract and mucous membranes. Symptoms may include coughing, shortness of breath. Remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, administer oxygen. Seek attention of a physician immediately.
- Ingestion may cause nausea, vomiting, diarrhea and difficulty in swallowing. If ingestion occurs, flush mouth with water and seek medical attention immediately. If person is conscious, induce vomiting. Never induce vomiting on an unconscious person.

STEP-BY-STEP INSTRUCTIONS:

- Gently shake or agitate the QMix™ 2in1 container prior to dispensing. Avoid creating excessive bubbles or foam inside container.
- Fill a fresh syringe with QMix™ 2in1 from either the 60 ml (w/ Luer lock syringe adapter) or 480 ml bottle (w/o Luer lock syringe adapter). Replace cap on container. Syringe not included.
- For 60 ml container only: Push the syringe tip fully into the bottle port (Luer lock). Twist syringe 1/4 turn clockwise to insure snug fit. Pull back on the plunger, withdrawing solution from the bottle into the syringe.
- For 480 ml container: The solution may be poured into a smaller container prior to withdrawal into a syringe.
- Attach an irrigation needle to syringe (e.g. side vented 30 gauge ProRinse Irrigation Needle with cap). Irrigation needle not included.
- Use up to 6.15% NaOCl for irrigation prior to use of QMix™ 2in1
- As with any final irrigation solution, rinse out the NaOCl with sterile water or saline.
- Remove cap from irrigation needle. Insert the needle into the canal being treated. Place the needle tip safely in canal (no more than 2 mm from apex). Express QMix™ 2in1 into canal.
- Irrigate for 60-90 seconds.
- Remove QMix™ 2in1 from canal and dispose.
- Dry the canal. Seal and obturate as normal.

Storage: STORAGE

- Store at room temperature. Keep out of direct sunlight. Do not refrigerate. Replace cap securely between uses.
- Do not use QMix™ 2in1 after expiration date.
- Do not store QMix™ 2in1 in an application syringe.

5719C0 (7/10)

PROPOSED LABELING (cont'd)

DRAFT ADVERTISING CLAIMS:

Claim	Verification
Kills planktonic bacteria (including Enterococcus faecalis)	(b)(4) Labs (Appendix A)
Removes smear layer from instrumented canal walls.	(b)(4)
Superior killing effectiveness: at least as effective as (b)(4)	(b)(4)
Equal or better effectiveness at removing smear layer in comparison with (b)(4)	(b)(4) (Appendix C)
More effective canal cleaning in preparation for obturation than (b)(4) (b)(4).	(b)(4)
Faster working time than BioPure MTAD.	(b)(4)
Single solution used as a final rinse after bleach for one-step smear layer removal and bacterial killing.	(b)(4)

SECTION 14. STERILIZATION AND SHELF LIFE

Sterilization:

The QMix™ 2in1 Irrigating Solution will not be supplied sterile and will not undergo sterilization during routine use.

Shelf Life:

QMix™ 2in1 Irrigating Solution is comprised of materials that have been previously cleared for marketing in higher concentrations than those present in QMix™ 2in1 Irrigating Solution.

(b)(4)



application is in support.

(b)(4)



temperature.

SECTION 15. BIOCOMPATIBILITY

Per ISO-10993-1, the biocompatibility requirements for an externally communicating device with limited (<24 hour) contact with the patient, are Cytotoxicity, Irritation and Sensitization.

CYTOTOXICITY

(b)(4)



(b)(4)



The Cytotoxicity reports can be found in Appendix D.

IRRITATION

(b)(4)



SENSITIZATION

(b)(4)



0054

SECTION 16. SOFTWARE

☒ This section is not applicable; no software contained in the medical device.

SECTION 17. ELECTROMAGNETIC COMPATIBILITY AND ELECTRICAL SAFETY

☒ This section is not applicable.

0055

000028

SECTION 18. PERFORMANCE TESTING – BENCH

Test #1

(b)(4)

(b)(4)



0056

Test #3

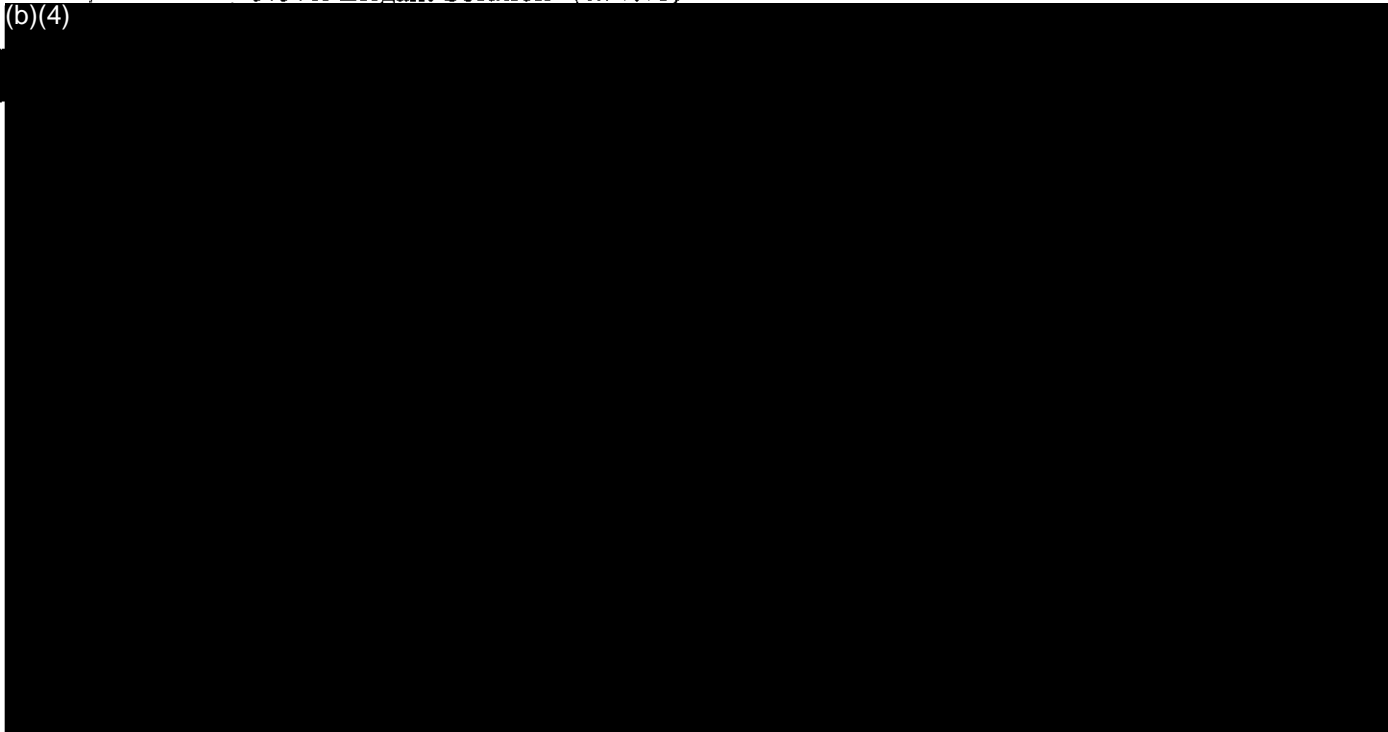
(b)(4)

(b)(4)

Study of Intracanal Bacterial Layer Removal by a

QMix™ 2in1 Irrigating Solution (ex vivo)

(b)(4)



SECTION 19. PERFORMANCE TESTING – ANIMAL

☒ This section is not applicable; no animal testing performed.

SECTION 20. PERFORMANCE TESTING – CLINICAL

☒ This section is not applicable; no clinical studies performed.

0058



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

**Certification of Compliance, under 42 U.S.C. § 282(j)(5)(B), with
Requirements of ClinicalTrials.gov Data Bank (42 U.S.C. § 282(j))**

(For submission with an application/submission, including amendments, supplements, and resubmissions, under §§ 505, 515, 520(m), or 510(k) of the Federal Food, Drug, and Cosmetic Act or § 351 of the Public Health Service Act.)

SPONSOR / APPLICANT / SUBMITTER INFORMATION

1. NAME OF SPONSOR/APPLICANT/SUBMITTER DENTSPLY International Inc.	2. DATE OF THE APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES 11/01/2010
3. ADDRESS (Number, Street, State, and ZIP Code) Susquehanna Commerce Center 221 West Philadelphia Street, Suite 60 York, PA 17404	4. TELEPHONE AND FAX NUMBERS (Include Area Code) (Tel.) 717-849-4229 (Fax) 717-849-4343

PRODUCT INFORMATION

5. **FOR DRUGS/BIOLOGICS:** Include Any/All Available Established, Proprietary and/or Chemical/Biochemical/Blood/Cellular/Gene Therapy Product Name(s)
FOR DEVICES: Include Any/All Common or Usual Name(s), Classification, Trade or Proprietary or Model Name(s) and/or Model Number(s)
(Attach extra pages as necessary)

_____	_____
_____	_____
_____	_____

APPLICATION / SUBMISSION INFORMATION

6. TYPE OF APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES <input type="checkbox"/> IND <input type="checkbox"/> NDA <input type="checkbox"/> ANDA <input type="checkbox"/> BLA <input type="checkbox"/> PMA <input type="checkbox"/> HDE <input checked="" type="checkbox"/> 510(k) <input type="checkbox"/> PDP <input type="checkbox"/> Other
7. INCLUDE IND/NDA/ANDA/BLA/PMA/HDE/510(k)/PDP/OTHER NUMBER (If number previously assigned) _____
8. SERIAL NUMBER ASSIGNED TO APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES _____

CERTIFICATION STATEMENT / INFORMATION

9. CHECK ONLY ONE OF THE FOLLOWING BOXES (See instructions for additional information and explanation) <input checked="" type="checkbox"/> A. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, do not apply because the application/submission which this certification accompanies does not reference any clinical trial. <input type="checkbox"/> B. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, do not apply to any clinical trial referenced in the application/submission which this certification accompanies. <input type="checkbox"/> C. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, apply to one or more of the clinical trials referenced in the application/submission which this certification accompanies and that those requirements have been met.
10. IF YOU CHECKED BOX C, IN NUMBER 9, PROVIDE THE NATIONAL CLINICAL TRIAL (NCT) NUMBER(S) FOR ANY "APPLICABLE CLINICAL TRIAL(S)," UNDER 42 U.S.C. § 282(j)(1)(A)(i), SECTION 402(j)(1)(A)(i) OF THE PUBLIC HEALTH SERVICE ACT, REFERENCED IN THE APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES (Attach extra pages as necessary) NCT Number(s): _____

The undersigned declares, to the best of her/his knowledge, that this is an accurate, true, and complete submission of information. I understand that the failure to submit the certification required by 42 U.S.C. § 282(j)(5)(B), section 402(j)(5)(B) of the Public Health Service Act, and the knowing submission of a false certification under such section are prohibited acts under 21 U.S.C. § 331, section 301 of the Federal Food, Drug, and Cosmetic Act.

Warning: A willfully and knowingly false statement is a criminal offense, U.S. Code, title 18, section 1001.

11. SIGNATURE OF SPONSOR/APPLICANT/SUBMITTER OR AN AUTHORIZED REPRESENTATIVE (Sign) 	12. NAME AND TITLE OF THE PERSON WHO SIGNED IN NO. 11 (Name) Helen Lewis (Title) Director, Corporate Compliance & Regulatory Affairs
13. ADDRESS (Number, Street, State, and ZIP Code) (of person identified in Nos. 11 and 12) Susquehanna Commerce Center 221 West Philadelphia Street, Suite 60 York, PA 17404	14. TELEPHONE AND FAX NUMBERS (Include Area Code) (Tel.) 717-849-4793 (Fax) 717-849-4343
	15. DATE OF CERTIFICATION 11/01/2010

**SECTION 22. Standards Data Report for 510(k)s
(Form FDA 3654)**

0060

Department of Health and Human Services
Food and Drug Administration
STANDARDS DATA REPORT FOR 510(k)s
(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☒ Traditional☐ Special☐ AbbreviatedSTANDARD TITLE¹

ISO 10993 Biological evaluation of medical devices-Part 10: Tests for irritation and sensitization 2002/(R) 2008

Please answer the following questions

Yes No

Is this standard recognized by FDA?² ☒ ☐FDA Recognition number³ # 2-87Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)? ☒ ☐Is a summary report⁴ describing the extent of conformance of the standard used included in the 510(k)? ☒ ☐
If no, complete a summary report table.Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device? ☒ ☐Does this standard include acceptance criteria? ☐ ☒
If no, include the results of testing in the 510(k).Does this standard include more than one option or selection of tests? ☒ ☐
If yes, report options selected in the summary report table.Were there any deviations or adaptations made in the use of the standard? ☐ ☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS)⁵? ☐ ☐Were deviations or adaptations made beyond what is specified in the FDA SIS? ☐ ☒
If yes, report these deviations or adaptations in the summary report table.Were there any exclusions from the standard? ☐ ☒
If yes, report these exclusions in the summary report table.Is there an FDA guidance⁶ that is associated with this standard? ☐ ☒
If yes, was the guidance document followed in preparation of this 510(k)? ☐ ☐

Title of guidance: ISO 10993 Biological evaluation of medical devices-Part 1: Evaluation and testing 2002, and ISO 7405

¹ The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

² Authority [21 U.S.C. 360d]; www.fda.gov/cdrh/stdsprog.html

³ <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

⁴ The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or

certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

⁵ The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

⁶ The online search for CDH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

**EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE**

STANDARD TITLE

ISO 10993 Biological evaluation of medical devices-Part 10: Tests for irritation and sensitization 2002

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER

Annex B

SECTION TITLE

Additional irritation tests

CONFORMANCE?

☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

B.4 Oral mucosa irritation test

DESCRIPTION

An assessment is made of the potential of the material under test to produce irritation of the oral tissue.

JUSTIFICATION

Standard test recommended per ISO 10993-1 2002

SECTION NUMBER

SECTION TITLE

CONFORMANCE?

☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER

SECTION TITLE

CONFORMANCE?

☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

* Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

Paperwork Reduction Act Statement

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to:

Center for Devices and Radiological Health
1350 Piccard Drive
Rockville, MD 20850

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

Department of Health and Human Services
Food and Drug Administration
STANDARDS DATA REPORT FOR 510(k)s
(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE¹

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

Please answer the following questions

Yes No

Is this standard recognized by FDA²? ☒ ☐

FDA Recognition number³ # 2-153

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)? ☒ ☐

Is a summary report⁴ describing the extent of conformance of the standard used included in the 510(k)? ☒ ☐
If no, complete a summary report table.

Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device? ☒ ☐

Does this standard include acceptance criteria? ☐ ☒
If no, include the results of testing in the 510(k).

Does this standard include more than one option or selection of tests? ☒ ☐
If yes, report options selected in the summary report table.

Were there any deviations or adaptations made in the use of the standard? ☐ ☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS)⁵? ☐ ☐

Were deviations or adaptations made beyond what is specified in the FDA SIS? ☐ ☒
If yes, report these deviations or adaptations in the summary report table.

Were there any exclusions from the standard? ☐ ☒
If yes, report these exclusions in the summary report table.

Is there an FDA guidance⁶ that is associated with this standard? ☐ ☒
If yes, was the guidance document followed in preparation of this 510(k)? ☐ ☐

Title of guidance: ISO 10993 Biological evaluation of medical devices-Part 1: Evaluation and testing 2002

¹ The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

² Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

³ <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

⁴ The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or

certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

⁵ The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

⁶ The online search for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE
ISO 10993 Biological evaluation of medical devices-Part 5: Tests for cytotoxicity: in vitro methods 2009

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER 8	SECTION TITLE Test Procedures	CONFORMANCE? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
---------------------	----------------------------------	--

TYPE OF DEVIATION OR OPTION SELECTED *

8.4 Test by indirect contact

DESCRIPTION

Agar Diffusion (Agar Overlay) This test allows a qualitative assessment of cytotoxicity.

JUSTIFICATION

Standard test recommended by ISO 10993-1:2002

SECTION NUMBER Annex B	SECTION TITLE Colony formation cytotoxicity test	CONFORMANCE? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
---------------------------	---	--

TYPE OF DEVIATION OR OPTION SELECTED *

B.2 Experimental Procedure

DESCRIPTION

MEM Elution Method

JUSTIFICATION

Standard test recommended by ISO 10993-1:2002

SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
----------------	---------------	---

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

* Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

Paperwork Reduction Act Statement

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Department of Health and Human Services
Food and Drug Administration
STANDARDS DATA REPORT FOR 510(k)s
(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☒ Traditional☐ Special☐ AbbreviatedSTANDARD TITLE¹

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

Please answer the following questions

Yes

No

Is this standard recognized by FDA²? ☒ ☐FDA Recognition number³ # 2-87Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)? ☒ ☐Is a summary report⁴ describing the extent of conformance of the standard used included in the 510(k)? ☒ ☐
If no, complete a summary report table.Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device? ☒ ☐Does this standard include acceptance criteria? ☐ ☒
If no, include the results of testing in the 510(k).Does this standard include more than one option or selection of tests? ☒ ☐
If yes, report options selected in the summary report table.Were there any deviations or adaptations made in the use of the standard? ☐ ☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS)⁵? ☐ ☐Were deviations or adaptations made beyond what is specified in the FDA SIS? ☐ ☒
If yes, report these deviations or adaptations in the summary report table.Were there any exclusions from the standard? ☐ ☒
If yes, report these exclusions in the summary report table.Is there an FDA guidance⁶ that is associated with this standard? ☐ ☒
If yes, was the guidance document followed in preparation of this 510(k)? ☐ ☐

Title of guidance: ISO 10993 Biological evaluation of medical devices-Part 1: Evaluation and testing 2002, and ISO 7405

¹ The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

² Authority [21 U.S.C. 380d], www.fda.gov/cdrh/stdsprog.html

³ <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

⁴ The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or

certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

⁵ The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

⁶ The online search for CDH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE		
STANDARD TITLE ISO 10993 Biological evaluation of medical devices-Part 10: Tests for irritation and sensitization 2010		
CONFORMANCE WITH STANDARD SECTIONS*		
SECTION NUMBER 7	SECTION TITLE Skin Sensitization Tests	CONFORMANCE? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED * 7.2 Murine Local Lymph Node Assay (LLNA)		
DESCRIPTION An assessment is made of the potential of the material under test to produce irritation of the oral tissue.		
JUSTIFICATION Acceptable method for device per ISO 10993-1 2002		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		
* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.		
* Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.		
Paperwork Reduction Act Statement Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: Center for Devices and Radiological Health 1350 Piccard Drive Rockville, MD 20850 <i>An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.</i>		

APPENDIX A

(b)(4) [REDACTED] Study- Protocol and Final Report

(b)(4) Test Reports: pgs 68-219 have been removed





COVER SHEET MEMORANDUM

From: Reviewer Name

Subject: 510(k) Number

To: The Record

Please list CTS decision code

☐ Refused to accept (Note: this is considered the first review cycle, See Screening Checklist
http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_5631/Screening%20Checklist%207%202%2007.doc)

☐ Hold (Additional Information or Telephone Hold).

☒ Final Decision (SE, SE with Limitations, NSE, Withdrawn, etc.).

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Page	Attach IFU	<input checked="" type="checkbox"/>	<input type="checkbox"/>
510(k) Summary /510(k) Statement	Attach Summary	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Truthful and Accurate Statement.	Must be present for a Final Decision	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Is the device Class III?		<input type="checkbox"/>	<input checked="" type="checkbox"/>
If yes, does firm include Class III Summary?	Must be present for a Final Decision	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Does firm reference standards? (If yes, please attach form from http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf)		<input checked="" type="checkbox"/>	<input type="checkbox"/>
Is this a combination product? (Please specify category _____, see http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC)		<input type="checkbox"/>	<input checked="" type="checkbox"/>
Is this a reprocessed single use device? (Guidance for Industry and FDA Staff – MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, http://www.fda.gov/cdrh/ode/guidance/1216.html)		<input type="checkbox"/>	<input checked="" type="checkbox"/>
Is this device intended for pediatric use only?		<input type="checkbox"/>	<input checked="" type="checkbox"/>
Is this a prescription device? (If both prescription & OTC, check both boxes.)		<input checked="" type="checkbox"/>	<input type="checkbox"/>
Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank?		<input type="checkbox"/>	<input checked="" type="checkbox"/>
Is clinical data necessary to support the review of this 510(k)? Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank? (If not, then applicant must be contacted to obtain completed form.)		<input type="checkbox"/>	<input checked="" type="checkbox"/>
Does this device include an Animal Tissue Source?		<input type="checkbox"/>	<input checked="" type="checkbox"/>
All Pediatric Patients age ≤ 21		<input type="checkbox"/>	<input checked="" type="checkbox"/>
Neonate/Newborn (Birth to 28 days)		<input type="checkbox"/>	<input checked="" type="checkbox"/>
Infant (29 days - < 2 years old)		<input type="checkbox"/>	<input checked="" type="checkbox"/>
Child (2 years - < 12 years old)		<input type="checkbox"/>	<input checked="" type="checkbox"/>
Adolescent (12 years - < 18 years old)		<input type="checkbox"/>	<input checked="" type="checkbox"/>
Transitional Adolescent A (18 - < 21 years old) Special considerations are being given to this group, different from adults age ≥ 21 (different device design or testing, different protocol procedures, etc.).		<input type="checkbox"/>	<input checked="" type="checkbox"/>

0004

Transitional Adolescent B (18 <= 21; No special considerations compared to adults => 21 years old)		✓
Nanotechnology		✓
Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance, http://www.fda.gov/cdrh/comp/guidance/169.html)	Contact OC.	✓

Regulation Number _____ Class* Unclassified Product Code 76 KJJ

(*If unclassified, see 510(k) Staff)

Additional Product Codes: _____

Review: [Signature] D3D3 2/14/11
 (Branch Chief) (Branch Code) (Date)

Final Review: [Signature] 2/14/11
 (Division Director) (Date)



Food and Drug Administration
Office of Device Evaluation
9200 Corporate Boulevard
Rockville, MD 20850

Premarket Notification [510(k)] Review
Traditional/Abbreviated

K103244

Date: February 9, 2011
To: The Record
From: Myra E. Browne, M.S., Biologist
Office/Division: ODE/DAGID
510(k) Holder: Dentsply International
Device Name: QMix 21N1 Endodontic Irrigating Solution
Contact: Ms. Helen Lewis
Phone: 717-845-7511
Fax: 717-849-4343
Email: hlewis@dentsply.com

Purpose and Submission Summary

The 510(k) holder would like to introduce QMix 2in1 Endodontic Irrigating Solution into interstate commerce.

QMix 2in1 Endodontic Irrigating Solution is a root canal cleansers used for the cleaning and disinfection of the root canal system after endodontic instrumentation.

QMix 2in1 Endodontic Irrigating Solution is substantially equivalent (SE) to legally marketed root canal cleansers because the information submitted by Dentsply International, demonstrates that the device has the same indication and technological characteristics as legally marketed root canal cleansers.

Administrative Requirements

	Yes	No	N/A
Indications for Use page (Indicate if: Prescription or OTC)	X		
Truthful and Accuracy Statement	X		
510(k) Summary or 510(k) Statement	X		
Standards Form	X		

0007

Indications for Use

QMix 2in1 Endodontic Irrigating Solution is a root canal cleanser used to clean and disinfect the root canal system after endodontic instrumentation.

The indication of QMix 2in1 Endo does not differ from that of legally marketed root canal cleansers.

Device Description/Formulation

	Yes	No	N/A
Is the device life-supporting or life sustaining?		X	
Is the device an implant (implanted longer than 30 days)?		X	
Does the device design use software?		X	
Is the device sterile?		X	
Is the device reusable (not reprocessed single use)?		X	
Are "cleaning" instructions included for the end user?			

The purpose of this 510(K) is to introduce a new product to market. No novel features have been introduced.

QMix 2 in 1 Endodontic Irrigating Solution is a standard root canal cleansers used for root canal lavage and debridement and as an irrigant for root canal instrumentation. The mechanical action of the solution moving in the root canal facilitates ease in the removal of debris and necrotic pulp tissue from the root canal. QMix 2in 1 is a premixed dual-action device that cleanses and disinfects the root canal system by removing smear layer and killing bacteria after endodontic instrumentation. The active ingredients in in QMix 2 in 1 Endodontic Irrigating Solution are: (b)(4). The mode of action for the (b)(4) is that it disrupts the bacterial cell membrane, killing the cell to ensure that it cannot reproduce or grow.

QMix 2 in1 Endodontic Irrigating Solution is packaged in HDPE screw-capped containers. It is available in 5ml, 60ml (with Luer lock syringe adapter) and 480 ml (without Luer lock syringe adapter) bulk-solution containers. The 5ml container will only be available free of charge as a sample. Syringes are not included with any of the containers.

The chemical formulation of QMix 2 in 1 Endodontic Irrigating Solution is as follows:

Chemical	%
(b)(4)	

0008

Contact History

The reviewer contacted the submitter by telephone on January 19, 2011 to request additional information for the devices (i.e. mode of action, indication for use, physical properties, etc.). The company responded to the requests on February 2, 2011.

Deficiencies

No deficiencies have been identified.

Labeling

QMix 2in1 Endodontic Irrigating Solution has been provided which includes instructions for use and an appropriate prescription statement as required by CFR 21.801.109. No unsubstantiated claims are purported.

Sterilization/Shelf Life/Reuse:

QMix 2in1 Endodontic Irrigating Solution will be provided non-sterile and is not intended to be sterilized before use.

Biocompatibility

The formulation of QMix 2in1 Endodontic Irrigating Solution includes no new components. This basic formulation is known to be biocompatible for this intended use. The company submitted cytotoxicity testing in which two versions of QMix 2in1 were tested for pH balance. These two versions were identical in chemical formulation and varied only in pH. The results of this cytotoxicity testing, irritation testing and sensitization testing conducted, demonstrated that QMix 2 in 1 Endodontic Irrigation Solution is as safe as other root canal cleansers.

Software

QMix 2in1 Endodontic Irrigating Solution contains no software.

Electromagnetic Compatibility and Electrical, Mechanical and Thermal Safety

QMix 2in1 Endodontic Irrigating Solution is not a mechanical or electrical device. Therefore, mechanical safety, electrical safety, EMC, and thermal safety are not applicable.

Performance Testing - Bench

Engineering performance test results are provided in Section III, Device Comparison.

0009

Performance Testing – Animal

Animal test results were not provided for QMix 2in1 Endodontic Irrigating Solution.

Performance Testing – Clinical

Human test results were not provided for QMix 2in1 Endodontic Irrigating Solution.

Device Comparison

Predicate Device: Biopure MTAD Root Canal Cleanser (K053167) of Dentsply International.

Physical property	QMix 2 in 1 Endodontic Irrigation Solution	Biopure MTAD Root Canal Cleanser (K053167)
pH	7.5	6.8
Chemical properties	Acidic solution during use	Slightly basic solution during use
Shelf life	2 years	2 years
% of bacteria killed (in vitro)	>or = 99.99	same

QMix 2in1 Endodontic Irrigating Solution is comparable to other legally marketed root canal cleansers on the market, especially the Biopure MTAD Root Canal Cleanser also manufactured by Dentsply International. These devices feature essentially the same intended use, composition and physical properties. The difference between QMix 2in1 and the predicate device is that the active ingredients (antimicrobial agents) are different. (b)(4)

(b)(4)

Reconfiguration of an existing formulation.

No new technological characteristics have been introduced in QMix 2in1 Endodontic Irrigating Solution that could affect its safety or effectiveness.

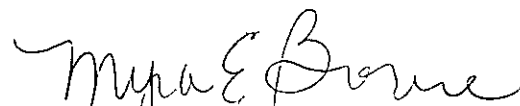
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Substantial Equivalence Discussion


	Yes	No
1. Same Indication Statement?	X	If YES = Go To 3
2. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?		If YES = Stop NSE
3. Same Technological Characteristics?	X	If YES = Go To 5
4. Could The New Characteristics Affect Safety Or Effectiveness?		If YES = Go To 6
5. Descriptive Characteristics Precise Enough?	X	If NO = Go To 8 If YES = Stop SE
6. New Types Of Safety Or Effectiveness Questions?		If YES = Stop NSE
7. Accepted Scientific Methods Exist?		If NO = Stop NSE
8. Performance Data Available?		If NO = Request Data
9. Data Demonstrate Equivalence?		Final Decision: SE

Recommendation

Regulation Number: Unclassified
Regulation Name: Root Canal Cleansers
Regulatory Class: Class II
Product Code: KJJ


Myra E. Browne, M.S., Biologist
Reviewer

2/9/11
Date


M. Susan Runner, DDS
Branch Chief

2/10/11
Date

0011



COVER SHEET MEMORANDUM

From: Reviewer Name

Subject: 510(k) Number

To: The Record

Please list CTS decision code

☐ Refused to accept (Note: this is considered the first review cycle, See Screening Checklist

http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_5631/Screening%20Checklist%207%202%2007.doc)

☒ Hold (Additional Information or Telephone Hold).

☐ Final Decision (SE, SE with Limitations, NSE, Withdrawn, etc.).

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Page	Attach IFU		
510(k) Summary /510(k) Statement	Attach Summary		
Truthful and Accurate Statement.	Must be present for a Final Decision		
Is the device Class III?			
If yes, does firm include Class III Summary?	Must be present for a Final Decision		
Does firm reference standards? (If yes, please attach form from http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf)			
Is this a combination product? (Please specify category _____, see http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC)			
Is this a reprocessed single use device? (Guidance for Industry and FDA Staff – MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, http://www.fda.gov/cdrh/ode/guidance/1216.html)			
Is this device intended for pediatric use only?			
Is this a prescription device? (If both prescription & OTC, check both boxes.)			
Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank?			
Is clinical data necessary to support the review of this 510(k)? Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank? (If not, then applicant must be contacted to obtain completed form.)			
Does this device include an Animal Tissue Source?			
All Pediatric Patients age<=21			
Neonate/Newborn (Birth to 28 days)			
Infant (29 days -< 2 years old)			
Child (2 years -< 12 years old)			
Adolescent (12 years -< 18 years old)			
Transitional Adolescent A (18 - <21 years old) Special considerations are being given to this group, different from adults age ≥ 21 (different device design or testing, different protocol procedures, etc.)			

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Transitional Adolescent B (18 -<= 21; No special considerations compared to adults => 21 years old)			
Nanotechnology			
Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance, http://www.fda.gov/cdrh/comp/guidance/169.html)	Contact OC.		

Regulation Number

Class*

Product Code

(*If unclassified, see 510(k) Staff)

Additional Product Codes:

Review:

(Branch Chief)

(Branch Code)

(Date)

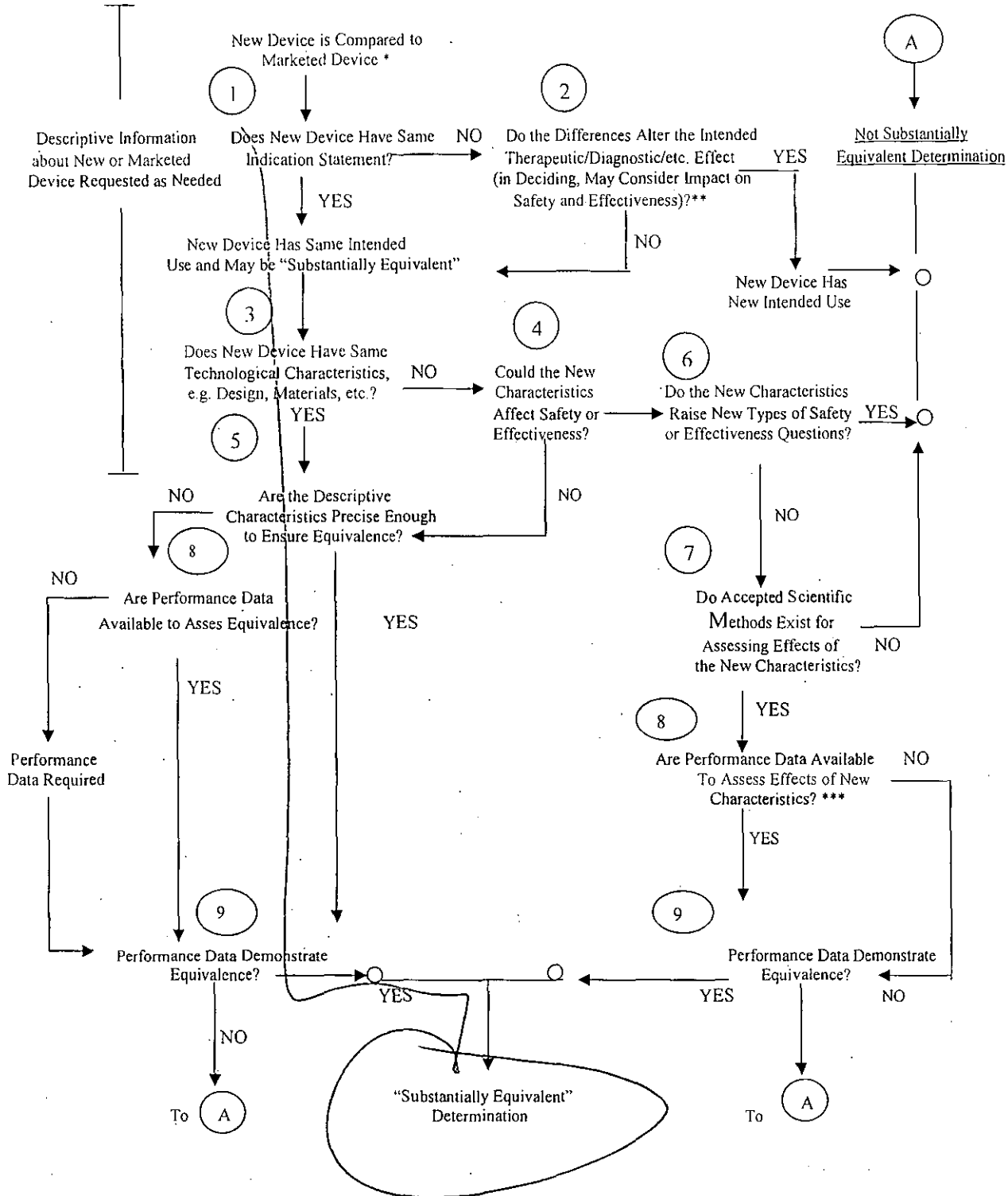
Final Review:

(Division Director)

(Date)

0021

510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS



* 510(k) Submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear.

** This decision is normally based on descriptive information alone, but limited testing information is sometimes required.

*** Data maybe in the 510(k), other 510(k)s, the Center's classification files, or the literature.

```

graph TD
    Start(( )) --> 1((1))
    1 --> Q1{Does New Device Have Same Indication Statement?}
    Q1 -- YES --> 3((3))
    Q1 -- NO --> 2((2))
    3 --> Q3{Does New Device Have Same Technological Characteristics, e.g. Design, Materials, etc.?}
    Q3 -- YES --> 5((5))
    Q3 -- NO --> 4((4))
    5 --> Q5{Are the Descriptive Characteristics Precise Enough to Ensure Equivalence?}
    Q5 -- YES --> 9((9))
    Q5 -- NO --> 8((8))
    8 --> Q8{Are Performance Data Available to Assess Equivalence?}
    Q8 -- YES --> 9
    Q8 -- NO --> A1((A))
    4 --> Q4{Do the Differences Alter the Intended Therapeutic/Diagnostic/etc. Effect (in Deciding, May Consider Impact on Safety and Effectiveness)?**}
    Q4 -- YES --> 6((6))
    Q4 -- NO --> 3
    6 --> Q6{Do the New Characteristics Affect Safety or Effectiveness?}
    Q6 -- YES --> 7((7))
    Q6 -- NO --> 4
    7 --> Q7{Do Accepted Scientific Methods Exist for Assessing Effects of the New Characteristics?}
    Q7 -- YES --> 8
    Q7 -- NO --> 9
    8 --> Q8_2{Are Performance Data Available To Assess Effects of New Characteristics? ***}
    Q8_2 -- YES --> 9
    Q8_2 -- NO --> A2((A))
    9 --> Q9{Performance Data Demonstrate Equivalence?}
    Q9 -- YES --> SE{Substantially Equivalent Determination}
    Q9 -- NO --> A1
    A1 --> A2
    A2 --> A3((A))
    
```

The flowchart outlines the process for determining substantial equivalence of a new medical device to a marketed device. It begins with a comparison of the new device to the marketed device. If the new device has the same indication statement, it proceeds to a comparison of technological characteristics. If these are also the same, the device is considered substantially equivalent. If not, the flowchart evaluates whether differences alter the intended therapeutic or diagnostic effect. If they do, it assesses whether new characteristics affect safety or effectiveness. If they do, it checks if accepted scientific methods exist for assessing these effects. If not, it checks if performance data are available to assess the effects of new characteristics. If they are, it checks if the performance data demonstrate equivalence. If they do, the device is considered substantially equivalent. If not, the device is not substantially equivalent. If the initial comparison of technological characteristics is not the same, the flowchart checks if the descriptive characteristics are precise enough to ensure equivalence. If they are, the device is considered substantially equivalent. If not, it checks if performance data are available to assess equivalence. If they are, it checks if the performance data demonstrate equivalence. If they do, the device is considered substantially equivalent. If not, the device is not substantially equivalent. If the initial comparison of indication statement is not the same, the flowchart checks if the differences alter the intended therapeutic or diagnostic effect. If they do, it checks if the new characteristics affect safety or effectiveness. If they do, it checks if accepted scientific methods exist for assessing these effects. If not, it checks if performance data are available to assess the effects of new characteristics. If they are, it checks if the performance data demonstrate equivalence. If they do, the device is considered substantially equivalent. If not, the device is not substantially equivalent. If the differences do not alter the intended therapeutic or diagnostic effect, the device is considered substantially equivalent.

*** Data maybe in the 510(k), other 510(k)s, the Center's classification files, or the literature.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center 6 WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

February 02, 2011

DENTSPLY INTL., INC.

SUSQUEHANNA COMMERCE CENTER 221 W PHILADELPHIA ST. STE 60

YORK, PENNSYLVANIA 17404

UNITED STATES

ATTN: HELEN LEWIS

510k Number: K103244

Product: QMIX 2IN1 ENDODONTIC IRRIGATOR

The additional information you have submitted has been received.

We will notify you when the processing of this submission has been completed or if any additional information is required. Please remember that all correspondence concerning your submission **MUST** be sent to the Document Mail Center at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm>. On August 12, 2005 CDRH issued the Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s. This guidance can be found at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm>. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

The Safe Medical Devices Act of 1990, signed on November 28, states that you may not place this device into commercial distribution until you receive a letter from FDA allowing you to do so. As in the past, we intend to complete our review as quickly as possible. Generally we do so in 90 days. However, the complexity of a submission or a requirement for additional information may occasionally cause the review to extend beyond 90 days. Thus, if you have not received a written decision or been contacted within 90 days of our receipt date you may want to check with FDA to determine the status of your submission.

Please ensure that whether you submit a 510(k) Summary as per 21 CFR 807.92, or a 510(k) Statement as per 21 CFR 807.93, it meets the content and format regulatory requirements.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301)796-7100 or at their toll-free number (800)638-2041, or contact the 510k staff at (301)796-5640.

Sincerely,

510(k) Staff

0012



DENTSPLY International
World Headquarters
Susquehanna Commerce Center
221 West Philadelphia Street
York, PA 17405-0872
(717) 845-7511 (voice)
(717) 849-4343 (fax)
www.dentsply.com

February 1, 2011

FDA CDRH DMC

Attn: Myra Brown

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

FEB 02 2011

Received

K-16

510(k) Number K103244 QMIX™ 2IN1 ENDODONTIC IRRIGATING SOLUTION

Response to Information Request Dated January 20, 2011

In response to your telephone call of January 19, 2011 and its accompanying letter dated January 20, 2011, DENTSPLY International is hereby submitting the additional information you requested for premarket notification submission K103244, QMIX™ 2in1 Endodontic Irrigating Solution, dated November 4, 2010.

Your requests for information in the January 19, 2011 phone call are presented in this letter in bold text. Our responses to your requests are provided below each section:

(1) Remove the words “kills bacteria” from the indications for use statement in your 510(k) submission, as this language is not in the indications for use for the predicate device.

Dentsply Response: We agree to remove “kills bacteria” from this 510(k)’s indications for use statement. The updated indications for use statement now reads as follows:

QMix™ 2in1 Endodontic Irrigating Solution is a premixed dual-action device that cleanses and disinfects the root canal system after endodontic instrumentation.

Both the 510(k) Summary and the Indications for Use Statement have been updated with this indications for use statement. Please find these updated 510(k) sections enclosed with this response.

(2) Clarify the cytotoxicity information provided in the 510(k) and put the information in layman’s terms.

Dentsply Response: Two versions of QMix were tested for cytotoxicity as indicated on page 161 of the application, (EBR 9210-999998-R210 “R” and “X”). These two versions are identical in formulation and vary only in pH. As indicated in the memo on page 49, version “R” is intended for commercial release, and version “X” is not. As expected for a disinfectant product, results of

0013

cytotoxicity testing naturally demonstrate cytotoxicity (Grade 4 on a 0-4 scale) for both versions of QMix™. As described on page 27 of the application, the same level of cytotoxicity was recorded for the predicate device, BioPure™ MTAD™, and other cleared root canal cleansers (e.g. those containing (b)(4), page 169).

(3) The chemical compositions of the subject device and the predicate device are different (b)(4). We also note a difference in the mode of action between the two devices. Please provide a better explanation of how the devices compare in their modes of action.

Dentsply Response: Both QMix™ and the predicate device, BioPure MTAD Root Canal Cleanser (K053167), have the same intended use. Both utilize antimicrobial agents to disinfect the root canal. BioPure MTAD(b)(4)

(b)(4) QMix™ 2in1(b)(4)

(b)(4) Both are effective against a broad spectrum of oral bacteria and both are used in devices cleared for use as endodontic disinfectants. The use of either QMix or BioPure MTAD results in a safe and effective cleansing and disinfection of the dental root canal.

Please contact me if you have any additional questions or concerns regarding this submission.

Sincerely,



Helen Lewis

Director of Corporate Compliance and Regulatory Affairs

Susquehanna Commerce Center

221 West Philadelphia Street

York, PA 17404

Phone: (717) 845-7511 (x54229)

Fax: (717) 849-4343

hlewis@dentsply.com

Enclosures

SECTION 4. INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K103244

Device Name: QMix™ 2in1 Endodontic Irrigating Solution

Indications for Use:

QMix™ 2in1 Endodontic Irrigating Solution is a premixed dual-action device that cleanses and disinfects the root canal system after endodontic instrumentation.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE—CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



SECTION 5. 510(k) SUMMARY

for

QMix™ 2in1 Endodontic Irrigating Solution

DENTSPLY International
World Headquarters
Susquehanna Commerce Center
221 West Philadelphia Street
York, PA 17405-0872
(717) 845-7511 (voice)
(717) 849-4343 (fax)
www.dentsply.com

1. Submitter Information:

DENTSPLY International
Susquehanna Commerce Center
221 West Philadelphia Street
York, PA 17405

Contact Person: Helen Lewis
Telephone Number: 717-849-4229
Fax Number: 717-849-4343

Date Prepared: 01 February 2011

2. Device Name:

- Proprietary Name: QMix™ 2in1 Endodontic Irrigating Solution
- Classification Name: Cleanser, Root Canal
- CFR Number: N/A
- Device Class: Unclassified
- Product Code: KJJ

3. Predicate Device:

BioPure MTAD Root Canal Cleanser, DENTSPLY International, K053167

4. Description of Device:

QMix™ 2in1 Endodontic Irrigating Solution is a premixed dual-action device that cleanses and disinfects the root canal system by removing the smear layer and killing bacteria after endodontic instrumentation.

5. Indications for Use:

QMix™ 2in1 Endodontic Irrigating Solution is a premixed dual-action device that cleanses and disinfects the root canal system after endodontic instrumentation.

6. Description of Safety and Substantial Equivalence:

Technological Characteristics.

All of the components found in QMix™ 2in1 Endodontic Irrigating Solution have been used in legally marketed devices and were found safe for dental use. We believe that prior use of components in legally marketed devices, the performance and biocompatibility data provided support the safety and effectiveness of QMix™ 2in1 Endodontic Irrigating Solution for the indicated uses.

Non-Clinical Performance Data.

The efficacy and biocompatibility of QMix™ 2in1 Endodontic Irrigating Solution was demonstrated *via* non-clinical *in vitro* and *ex vivo* studies.

Clinical Performance Data.

No clinical studies were conducted on this device.

Conclusion as to Substantial Equivalence

QMix™ 2in1 Endodontic Irrigating Solution, to be manufactured by DENTSPLY International, is substantially equivalent to the currently cleared and marketed BioPure MTAD root canal cleanser.