Records Processed under FOIA Request 2016-3415; Released by CDRH on 08/17/2016 K151763

MILLENNIUM DENTAL TECHNOLOGIES, INC.

Cover Letter

June 22, 2015

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

FDA CDRH DMC
JUN 29 2015
Received

Re: 510(K) Submission – Traditional 510(k)
Millennium Dental Technologies, Inc.
Establishment Registration Number: 2031763
Device Common Name: Nd:YAG Pulsed Dental Laser
Trade Name: PerioLase Nd:YAG Pulsed Dental Laser System
Classification Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Product Code: GEX
Classification Regulation: 21 CFR 878.4810
Classification Panel: General and Plastic Surgery
Device Class: Class II
Reason for Submission: Request Clearance for New Clinical Outcome Claim

The enclosed Traditional 510(k) Premarket Notification is submitted on behalf of Millennium Dental Technologies, Inc., Establishment Registration Number 2031763. This document complies with 21 CFR, Part 807, Subpart E, premarket notification.

The eCopy is an exact duplicate of the paper copy.

The ***PerioLase Nd:YAG Pulsed Dental Laser System*** (common name: Nd:YAG pulsed dental laser), manufactured by Millennium Dental Technologies, Cerritos, California, has been previously cleared to market under K010771, K014272, and K030290. This application is submitted to request clearance for a new clinical outcome claim:

> Periodontal regeneration – true regeneration of the attachment apparatus (new cementum, new periodontal ligament, and new alveolar bone) on a previously diseased root surface when used specifically in the LANAP® Protocol.

We believe the attached summary of a human histological study supports this new outcome claim which requires no changes to the device or software previously cleared for market.

Recommendations for this class II device are Classification Regulation Number 878.4810, General & Plastic Surgery Review Panel, Product Code GEX.

10945 South Street, Suite 104-A
Cerritos, CA 90703
www.millenniumdental.com

Phone: 1-888-49-LASER
Phone: 1-562-860-2908
Fax: 1-562-860-2429

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Design and Use of the Device

Question	Yes	No
Is the device intended for prescription use (21 CFR 801 Subpart D)?	X	
Is the device intended for over-the-counter use (21 CFR 807 Subpart C)?		X
Does the device contain components derived from a tissue or other biologic source?		X
Is the device provided sterile?		X
Is the device intended for single use?		X
Is the device a reprocessed single use device?		X
Does the device contain a drug?		X
Does the device contain a biologic?		X
Does the device use software?	X	
Does the submission include clinical information?	X	
Is the device implanted?		X

Millennium Dental Technologies, Inc. intends to fully comply with the FDA mandatory performance standards (section 510 of the FD&C Act and section 21 CFR 1010) and consensus standards for medical laser devices.

The information contained in this document is confidential and proprietary. Knowledge of this project and product line has been restricted to Millennium Dental Technologies, Inc. employees and agents only. None of this information is public. The complete document should not be released through Freedom of Information Act requests or any other way. We request that Millennium Dental Technologies, Inc. be notified by FDA if there is an FOI request filed for this document. Selected confidential and/or proprietary information must be deleted before any part of the document is released.

David M. Harris, PhD, is the official correspondent for Millennium Dental Technologies, Inc. for this submission. Please direct any questions or correspondence about this submission to our attention at the telephone number or address indicated.

Sincerely,

David M. Harris, PhD
Chief Science Officer

Millennium Dental Technologies, Inc.
10945 South Street, Suite 104-A
Cerritos, CA 90703

Office: 562-860-2908
Mobile: 510-502-3345
Fax: 562-860-2429 and 510-372-0326

www.lanap.com
dharris@lanap.com – Dr Harris

Enclosure: CD with electronic version of this application.
cc: Executive Committee, Millennium Dental Technologies, Inc.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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MILLENNIUM DENTAL TECHNOLOGIES, INC.

510(k) Application

PerioLase Nd:YAG Pulsed Dental Laser System

for

New Clinical Outcome Claim in Dentistry

June 22, 2015

Please Note

The information contained in this document is **confidential and proprietary**. Knowledge of this project and product line has been restricted to Millennium Dental Technologies, Inc. employees and agents only. None of this information is public (except the 2-page "Indications for Use" Form 3881 under Tab 6 and the 4-page "510(k) Summary" under Tab 7, pending FDA's granting marketing clearance for the new clinical outcome claim). The complete document should not be released through Freedom of Information Act requests or any other way. We request that Millennium Dental Technologies, Inc. be notified by FDA if there is an FOI request filed for this document. Selected confidential and/or proprietary information must be deleted before any part of the document is released.

Contact:

David M. Harris, PhD
Chief Science Officer

Millennium Dental Technologies, Inc.
10945 South Street, Suite 104-A
Cerritos, CA 90703

Office: 562-860-2908
Mobile: 510-502-3345
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Form Approved OMB No. 0910-0511 Expiration Date April 30, 2016. See Instructions for OMB Statement.

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION **MEDICAL DEVICE USER FEE COVER SHEET**	PAYMENT IDENTIFICATION NUMBER: (b)(4) 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/coversheet.html

1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code)	2. CONTACT NAME
MILLENNIUM DENTAL TECHNOLOGIES INC 10945 SOUTH STREET SUITE 104 A CERRITOS CA 90703 US	Janie DeMatteo 2.1 E-MAIL ADDRESS jdematteo@lanap.com 2.2 TELEPHONE NUMBER (include Area code) 562-8602908
1.1 EMPLOYER IDENTIFICATION NUMBER (EIN) *****3283	2.3 FACSIMILE (FAX) NUMBER (Include Area code)

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/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm345263.htm

Select an application type:	3.1 Select a center
[X] Premarket notification(510(k)); except for third party	[X] CDRH
[ ] 513(g) Request for Information	[ ] CBER
[ ] Biologics License Application (BLA)	3.2 Select one of the types below
[ ] Premarket Approval Application (PMA)	[X] Original Application
[ ] Modular PMA	Supplement Types:
[ ] Product Development Protocol (PDP)	[ ] Efficacy (BLA)
[ ] Premarket Report (PMR)	[ ] Panel Track (PMA, PMR, PDP)
[ ] 30-Day Notice	[ ] Real-Time (PMA, PMR, PDP)
	[ ] 180-day (PMA, PMR, PDP)

4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status)

[ ] YES, I meet the small business criteria and have submitted the required qualifying documents to FDA

[X] 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?

[X] 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.)

[ ] 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.

[ ] This application is the first PMA submitted by a qualified small business, including any affiliates

[ ] The sole purpose of the application is to support conditions of use for a pediatric population

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[ ] This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only	[ ] 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).

[ ] YES [X] NO

PAPERWORK REDUCTION ACT STATEMENT

Public reporting burden for this collection of information is estimated to average 18 minutes 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 the address below.

Department of Health and Human Services, Food and Drug Administration, Office of Chief Information Officer, 8455 Colesville Road, COLE-14-14253 Silver Spring, MD 20993-0002
[Please do NOT return this form to the above address, except as it pertains to comments on the burden estimate.]

8. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION

(b)(4) 10-Nov-2014

Form FDA 3601 (01/2007)

"Close Window" Print Cover sheet

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Acceptance Checklist
for Traditional 510(k)s

(should be completed within 15 days of DCC receipt)

The following information is not intended to serve as a comprehensive review.

510(k) Number: _____ **Date Received by DCC:** _____

Lead Reviewer Name: _____ **Branch:** _____ **Division:** _____ **Office:** _____

Note: If an element is left blank on the checklist, it does not mean the checklist is incomplete; it means the reviewer did not assess the element during RTA and that element will be assessed during substantive review.

Preliminary Questions		
Answers in the shaded blocks indicate consultation with Center advisor is needed.	**Yes**	**No**
1. Is the product a device (per section 201(h) of the FD&C Act) or a combination product (per 21 CFR 3.2(e)) with a device constituent part subject to review in a 510(k)? If it appears not to be a device (per section 201(h) of the FD&C Act) or such a combination product, or you are unsure, consult with the CDRH Jurisdictional Officer or the CBER Office Jurisdiction Liaison to determine the appropriate action, and inform division management. *Provide a summary of the Jurisdictional Officer's/Liaison's determination.* If the product does not appear to be a device or such a combination product, mark "No."	Yes	
Comments:		
2. Is the application with the appropriate Center? If the product is a device or a combination product with a device constituent part, is it subject to review by the Center in which the submission was received? If you believe the application is not with the appropriate Center or you are unsure, consult with the CDRH Jurisdictional Officer or CBER Office Jurisdiction Liaison to determine the appropriate action and inform your division management. *Provide a summary of the Jurisdictional Officer's/Liaison's determination.* If application should not be reviewed by your Center mark "No."	Yes	
Comments:		
3. If a Request for Designation (RFD) was submitted for the device or combination product with a device constituent part and assigned to your center, identify the RFD # and confirm the following:		

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

a) Is the device or combination product the same (e.g., design, formulation) as that presented in the RFD submission? **b) Are the indications for use for the device or combination product identified in the 510(k) the same as those identified in the RFD submission?** If you believe the product or the indications presented in the 510(k) have changed from the RFD, or you are unsure, consult with the CDRH Jurisdictional Officer or appropriate CBER Jurisdiction Liaison to determine the appropriate action and inform your division management. *Provide summary of Jurisdictional Officer's/Liaison's determination.* If the answer to either question above is no, mark "No." If there was no RFD, skip this question.		
Comments:		
4. Is this device type eligible for a 510(k) submission? If a 510(k) does not appear to be appropriate (e.g., Class III type and PMA required, or Class I or II type and 510(k)-exempt), you should consult with the CDRH 510(k) Program Director or appropriate CBER staff during the acceptance review. If 510(k) is not the appropriate regulatory submission, mark "No."	Yes	
Comments:		
5. Is there a pending PMA for the same device with the same indications for use? If yes, consult division management and the CDRH 510(k) Program Director or appropriate CBER staff to determine the appropriate action.		No
Comments:		
6. If clinical studies have been submitted, is the submitter the subject of an Application Integrity Policy (AIP)? If yes, consult with the CDRH Office of Compliance/Division of Bioresearch Monitoring (OC/DBM - BIMO) or CBER Office of Compliance and Biologics Quality/Division of Inspections and Surveillance/Bioresearch Monitoring Branch (OCBQ/DIS/BMB) to determine the appropriate action. Check on web at http://www.fda.gov/ICECI/EnforcementActions/ApplicationIntegrityPolicy/ucm134453.htm.		No

If the answer to 1 or 2 appears to be "No," then stop review of the 510(k) and issue the "Original Jurisdictional Product" letter.
If the answer to 3a or 3b appears to be "No," then stop the review and contact the CDRH Jurisdictional Officer or CBER Office of Jurisdiction Liaison.
If the answer to 4 is "No", the lead reviewer should consult division management and other Center resources to determine the appropriate action.
If the answer to 5 is "Yes," then stop review of the 510(k), contact the CDRH 510(k) Staff and PMA Staff, or appropriate CBER staff.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

If the answer to 6 is "Yes," then contact CDRH/OC/DBM – BIMO or CBER/OCBQ/DIS/BMB, provide a summary of the discussion with the BIMO Staff, and indicate BIMO's recommendation/action.

Organizational Elements *Failure to include these items alone generally should not result in an RTA designation*		
	Yes	**No**
a. Submission contains Table of Contents Page 4-1	☒	☐
b. Each section is labeled (e.g., headings or tabs designating Device Description section, Labeling section, etc.)	☒	☐
c. All pages of the submission are numbered *All pages should be numbered in such a manner that information can be referenced by page number. This may be done either by consecutively numbering the entire submission, or numbering the pages within a section (e.g., 12-1, 12-2…).*	☒	☐
d. Type of 510(k) is identified– traditional, abbreviated, or special *If type of 510(k) is not designated, review as a traditional* Sections 2 & 3	☒	☐
Comments:		

Elements of a Complete Submission (RTA Items) **(21 CFR 807.87 unless otherwise indicated)** Submission should be designated RTA if not addressed					
Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.					
	• Any "No" answer will result in a "Refuse to Accept" decision. • Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.			**Yes**	**N/A**	**No**
A.	**Administrative**					
	1.	All content used to support the submission is written in English (including translations of test reports, literature articles, etc.)		☒		☐
		Comments:				
	2.	Submission identifies the following (such as in CDRH Premarket Review Submission Cover Sheet (Form 3514) or 510(k) cover letter):		☒		☐
		a.	Device trade name or proprietary name Sections 2 & 3	☒		☐
		b.	Device common name Sections 2 & 3	☒		☐

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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	• Any "No" answer will result in a "Refuse to Accept" decision. • Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.			**Yes**	**N/A**	**No**
		c.	Device class and panel or Classification regulation or Statement that device has not been classified with rationale for that conclusion	Sections 2 & 3	☒		☐
		Comments:					
	3.	Submission contains Indications for Use Statement with Rx and/or OTC designated (see also 21 CFR 801.109) *Submitter should use format appropriate for the reviewing Center/Office (CDRH/ODE, CDRH/OIVD, CBER/OBRR, CBER/OCTGT). If not provided in correct format, request the correct format during substantive review.*		See comments immediately below	☒		☐
		Comments:		Indications for Use: Sections 6, 7, 10, 11, App.A sect.5 Prescription only: Pages 3-2, 9-1, 11-4, App.A p.1-2			
	4.	Submission contains 510(k) Summary or 510(k) Statement *Either a) or b) must be answered "Yes" to be considered complete. Identify any missing element(s) in Comments.*		Section 7	☒		☐
		a.	Summary contains all elements per 21 CFR 807.92 *See also 510(k) Summary Checklist*	Section 7	☒	☐	☐
		b.	Statement contains all elements per 21 CFR 807.93		☐	☒	☐
		Comments:					
	5.	Submission contains Truthful and Accuracy Statement per 21 CFR 807.87(k) *See recommended format. Select "Yes" if statement is present and includes the text in the recommended format, and is signed by a responsible person of the firm (not consultant).*		Section 8	☒		☐
		Comments:					

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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.					
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	6.	Submission contains Class III Summary and Certification *See recommended content. Form should be signed by a responsible person of the firm, not a consultant. Select "N/A" only if submission is not a Class III 510(k).*	☐	☒	☐
		Comments:			
	7.	Submission contains clinical data *Select "N/A" if the submission does not contain clinical data. If "N/A" is selected, parts a and b below are omitted from the checklist.*	☐	☒	
		a. Submission includes completed Financial Certification (FDA Form 3454) or Disclosure (FDA Form 3455) information for each covered clinical study included in the submission. *Select "N/A" if the submitted clinical data is not a "covered clinical study" as defined in the Guidance for Industry-Financial Disclosures by Clinical Investigators*	☐	☐	☐
		b. Submission includes completed Certification of Compliance with requirements of ClinicalTrials.gov Data Bank (FDA Form 3674) (42 U.S.C. 282(j)(5)(B)) for each applicable device clinical trial included in the submission. *Select "N/A" if the submitted clinical data is not an "applicable device clinical trial" as defined in Title VIII of FDAAA, Sec. 801(j)*	☐	☐	☐
		Comments: The submitted data are from a single-arm, human histological study evaluating the clinical outcome of a treatment protocol. It is not a "covered clinical study" per the definition in 21 CFR 54.2(e).			
	8.	If submission references use of a national or international standard as part of demonstration of substantial equivalence, submission contains complete Standards Data Report for 510(k)s (FDA Form 3654) Section 17 *There should be a completed form for each referenced national or international standard.* *Select "N/A" only if submission does not reference any standards.*	☒	☐	☐

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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.					
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		Comments:				
	9.	The submission identifies prior submissions for the same device for which FDA provided feedback related to the data or information needed to support substantial equivalence (e.g., submission numbers for Pre-Submission, IDE, prior not substantially equivalent (NSE) determination, prior 510(k) that was deleted or withdrawn) or states that there were no prior submissions for the subject device. *This information may be included in the Cover Letter (i.e., as a statement that there were no prior submissions for the device or a listing of the number(s) of the prior submissions). Alternatively, a list of submission numbers may be found in Section F (prior related submissions section) of the CDRH Coversheet form (Form 3514) to address this criterion. Please be advised that if this section of the form is left blank, it should not be considered a statement that there were no prior submissions.*		☒ Sections 2 & 3		☐
		a.	If there were prior submissions, the submitter has identified where in the current submission any issues related to a determination of substantial equivalence outlined in prior communications are addressed. *To address this criterion, the submission may include a separate section with the prior submission number(s), a copy of the FDA feedback (e.g., letter, meeting minutes), and a statement of how or where in the submission this prior feedback was addressed. Note that the adequacy of how the feedback was addressed should be assessed during the substantive review.* For additional information regarding the Pre-Submission process, please refer to the Draft Guidance "Medical Devices: The Pre-Submission Program and Meetings with FDA Staff." (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm310375.htm). Once finalized, this guidance will represent the	☐	☒	☐

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	• Any "No" answer will result in a "Refuse to Accept" decision. • Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.			**Yes**	**N/A**	**No**
			Agency's current thinking on this topic. *Select "N/A" if the submitter states there were no prior submissions in criterion above.*			
		Comments:				
B.	**Device Description**					
	10.	a.	If there are requirements regarding the device description, such as special controls, in a device-specific regulation that are applicable to the device, the submission includes device description information to establish that the submitter has followed the device-specific requirement. *Select "N/A" if there are no applicable requirements in a device-specific regulation. Select "No" if the submission does not include a rationale for any omitted information. Note that the adequacy of how such requirements have been addressed should be assessed during the substantive review.*	☒ p.11-4	☐	☐
		b.	If there is a device-specific guidance, other than a special controls guidance document, applicable to the device, the submission includes device description information to establish that the submitter has addressed the recommendations or otherwise has met the applicable statutory or regulatory criteria through an alternative approach. *Select "N/A" if there is no applicable device-specific guidance. Select "No" if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how recommendations in a device-specific guidance, etc., have been addressed should be assessed during the substantive review.*	☒ p.11-4	☐	☐
		Comments:				

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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.						
	• Any "No" answer will result in a "Refuse to Accept" decision. • Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.			**Yes**	**N/A**	**No**
	11.	Descriptive information is present and consistent within the submission (e.g., the device description section is consistent with the device description in the labeling), including:				
		a.	A description of the principle of operation and mechanism of action for achieving the intended effect.	☒ p.10-2		☐
		b.	A description of proposed conditions of use, such as surgical technique for implants; anatomical location of use; user interface; how the device interacts with other devices; and/or how the device interacts with the patient.	☒ p.10-2 & App.A		☐
		c.	A list and description of each device for which clearance is requested. *Select "N/A" if there is only one device or model. "Device" may refer to models, part numbers, or various sizes, etc.*	☐	☒	☐
		Comments:				
	12.	Submission contains representative engineering drawing(s), schematics, illustrations and/or figures of the device that are clear, legible, labeled, and include dimensions. *In lieu of drawings, schematics, etc. of each device to be marketed, "representative" drawings, etc. may be provided, where "representative" is intended to mean that the drawings, etc. provided capture the differences in design, size, and other important characteristics of the various models, sizes, or versions of the device(s) to be marketed.* *Select "N/A" if the submitter provided a rationale for why the submission does not contain engineering drawings, schematics, etc. (e.g., device is a reagent and figures are not pertinent to describe the device).*		p. 10-2, App.A & B, K010771	☒	☐	☐
		Comments:				

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	• Any "No" answer will result in a "Refuse to Accept" decision. • Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.			**Yes**	**N/A**	**No**
	13.	If device is intended to be marketed with multiple components, accessories, and/or as part of a system, *Select "N/A" if the device is not intended to be marketed with multiple components, accessories, and/or as part of a system.*			☐	
		a.	Submission includes a list of all components and accessories to be marketed with the subject device. p.10-2, App.A sect.2.1	☒		☐
		b.	Submission includes a description (as detailed in item 11.a. and b. and 12 above) of each component or accessory. *Select "N/A" if the component(s)/accessory(ies) has been previously cleared, or is exempt, and the proposed indications for use are consistent with the cleared indications.*	☐	☒	☐
		c.	A 510(k) number is provided for each component or accessory that received a prior 510(k) clearance. *Select "N/A" if the submission states that the component(s)/ accessory(ies) does not have a prior 510(k) clearance or the component(s)/accessory(ies) is 510(k) exempt.*	☒ p.10-2	☐	☐
		Comments:				
C.	**Substantial Equivalence Discussion**					
	14.	Submitter has identified a predicate(s) device		☒		☐
		a.	Predicate's 510(k) number, trade name, and model number (if applicable) provided. Sections 3, 7, 11 For predicates that are preamendments devices, information is provided to document preamendments status. *Information regarding documenting preamendment status is available online (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidan*	☒		☐

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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.						
	• Any "No" answer will result in a "Refuse to Accept" decision. • Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.			**Yes**	**N/A**	**No**
			ce/ComplianceActivities/ucm072746.htm).			
		b.	The identified predicate(s) is consistent throughout the submission (i.e., the predicate(s) identified in the Substantial Equivalence section is the same as that listed in the 510(k) Summary (if applicable) and that used in comparative performance testing.	☒ Sections 3, 7, 11		☐
		Comments:				
	15.	Submission includes a comparison of the following for the predicate(s) and subject device				
		a.	Indications for use Section 11	☒		☐
		b.	Technology, including features, materials, and principles of operation Sections 7, 10, 11	☒		☐
		Comments:				
	16.	Submission includes an analysis of why any differences between the subject device and predicate(s) do not render the device NSE (e.g., does not constitute a new intended use; and any differences in technological characteristics are accompanied by information that demonstrates the device is as safe and effective as the predicate and do not raise different questions of safety and effectiveness than the predicate), affect safety or effectiveness, or raise different questions of safety and effectiveness (see section 513(i)(1)(A) of the FD&C Act and 21 CFR 807.87(f)) *If there is no difference between the subject and predicate(s) with respect to indications for use or technology, this should be explicitly stated, in which case "N/A" should be selected. Select "No" only if the submission does not include an analysis of differences as described above or a statement that there are no differences. Note that the adequacy of the analysis should be assessed during the substantive review; only the presence of such an analysis is required for acceptance. In addition, note that due to potential differences in*		☒ p.7-3 & 7-4 & Section 11	☐	☐

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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.					
	• Any "No" answer will result in a "Refuse to Accept" decision. • Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.			**Yes**	**N/A**	**No**
		manufacturing that may not be known to the submitter, the fact that no differences are identified does not necessarily mean that no performance testing is needed.				
		Comments:				
D.	**Proposed Labeling (see also 21 CFR part 801)** *If in vitro diagnostic (IVD) device, criteria 17, 18, and 19 may be omitted. These criteria will be omitted from the checklist if "N/A" is selected. IVD labeling is addressed in section 21 below.*				☐	
	17.	Submission includes proposed package labels and labeling (e.g., instructions for use, package insert, operator's manual) that include a description of the device, its intended use, and the directions for use		☒ Section 9 & App.A		☐
		a.	Indications for use are stated in labeling and are identical to Indications for Use form and 510(k) Summary (if 510(k) Summary provided)	☒ Sections 6, 7, 9 & App.A		☐
		b.	Submission includes directions for use that - include statements of all conditions, purposes or uses for which the device is intended (e.g., hazards, warnings, precautions, contraindications) (21 CFR 801.5) AND - Includes directions for layperson (see 21 CFR 801.5) OR submission states that device qualifies for exemption per 21 CFR 801 Subpart D	☒ Section 9 & App.A		☐
		Comments:				
	18.	If indicated for prescription use, labeling includes the prescription use statement (see 21 CFR 801.109(b)(1)) or "Rx only" symbol [See also Alternative to Certain Prescription Device Labeling Requirements] *Select "N/A" if not indicated for prescription use.*		☒ Section 9 & App.A	☐	☐ sect.1.1

Records Processed under FOIA Request 2016-3415; Released by CDRH on 08/17/2016

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	• Any "No" answer will result in a "Refuse to Accept" decision. • Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.			**Yes**	**N/A**	**No**
		Comments:				
	19.	General labeling provisions				
		a.	Labeling includes name and place of business of the manufacturer, packer, or distributor (21 CFR 801.1) Section 9 & App.A title page & sect.1.3.M	☒		☐
		b.	Labeling includes device common or usual name (21 CFR 801.61) *Select "N/A" if device is for prescription use only.*	☐	☒	☐
		Comments:				
	20.	a.	If there are requirements regarding labeling, such as special controls, in a device-specific regulation that are applicable to the device, the submission includes labeling to establish that the submitter has followed the device-specific requirement. Section 9 & App.A *Select "N/A" if there are no applicable requirements in a device-specific regulation. Select "No" if the submission does not include a rationale for any omitted information. Note that the adequacy of how such requirements have been addressed should be assessed during the substantive review.*	☒	☐	☐
		b.	If there is a device-specific guidance, other than a special controls guidance document, applicable to the device, the submission includes labeling to establish that the submitter has addressed the recommendations or otherwise has met the applicable statutory or regulatory criteria through an alternative approach. Section 9 & App.A *Select "N/A" if there is no applicable device-specific guidance. Select "No" if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how recommendations in a device-specific guidance have been addressed should be assessed during the substantive review.*	☒	☐	☐

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		c.	If there is a special controls document applicable to the device, the submission includes labeling to establish that the submitter has complied with the particular mitigation measures set forth in the special controls document or uses alternative mitigation measures but provides a rationale to demonstrate that those alternative measures identified by the firm will provide at least an equivalent assurance of safety and effectiveness. *Select "N/A" if there is no applicable special controls document. Select "No" if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how mitigation measures in a special controls document have been addressed should be assessed during the substantive review.*	☒ Section 9	☐ & App A	☐
		Comments:				
	21.	If the device is an in vitro diagnostic device, provided labeling includes all applicable information required per 21 CFR 809.10. *Select "N/A" if not an in vitro diagnostic device.*		☐	☒	☐
E.	**Sterilization** *If in vitro diagnostic (IVD) device and sterilization is not applicable, select "N/A." The criteria in this section will be omitted from the checklist if "N/A" is selected.*				☐	
	Submission states that the device and/or accessories are: (*one of the below must be checked*) ☐ provided sterile ☒ provided non-sterile but sterilized by the end user p.10-3 ☐ non-sterile when used This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination. *If "non-sterile when used" is selected, the sterility-related criteria below are omitted from*					☐

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	the checklist. *If information regarding the sterility status of the device is not provided, select "No."*					
	Comments:					
	22.	Assessment of the need for sterilization information				
		a.	Identification of device, and/or accessories, and/or components that are provided sterile. p.10-3 & App.A	☒	☐	☐
		b.	Identification of device, and/or accessories, and/or components that are end user sterilized p.10-3 & App.A	☒	☐	☐
		c.	Identification of device, and/or accessories, and/or components that are reusable and cleaning/disinfection instructions are provided. p.10-3 & App.A	☒	☐	☐
		Comments:				
	23.	If the device, and/or accessory, and/or a component is provided sterile: *Select "N/A" if no part of the device, accessories, or components is provided sterile, otherwise complete a-e below.*			☒	
		a.	Sterilization method is stated for each component (including parameters such as dry time for steam sterilization, radiation dose, etc.)	☐		☐
		b.	A description of method to validate the sterilization parameters (e.g., half-cycle method and full citation of FDA-recognized standard, including date) is provided for each proposed sterilization method. *Note, the sterilization validation report is not required.*	☐		☐
		c.	For devices sterilized using chemical sterilants such as ethylene oxide (EO) and hydrogen peroxide, submission states maximum	☐	☐	☐

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	• Any "No" answer will result in a "Refuse to Accept" decision. • Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.			**Yes**	**N/A**	**No**
			levels of sterilant residuals remaining on the device and sterilant residual limits. *Select "N/A" if not sterilized using chemical sterilants.*			
		d.	Submission includes description of packaging and packaging contents (e.g., if multiple devices are included within the same package, Tyvek packaging, etc.)	☐		☐
		e.	Sterility Assurance Level (SAL) stated	☐		☐
		Comments:				
	24.	If the device, and/or accessory, and/or a component is end user sterilized: *Select "N/A" if no part of the device, accessories, or components are end user sterilized, otherwise complete a-d below.*			☐	
		a.	Sterilization method is stated for each component (including parameters such as dry time for steam sterilization, radiation dose, etc.)	☒ p.10-3		☐
		b.	A description of method to validate the sterilization parameters (e.g., half-cycle method and full citation of FDA-recognized standard, including date) is provided for each proposed sterilization method. *Note, the sterilization validation is not required.*	☒ p.10-3		☐
		c.	Submission includes description of packaging and packaging contents (e.g., if multiple devices are included within the same package, Tyvek packaging, etc.)	☒ p.10-3		☐
		d.	Submission includes sterilization instructions for end user p.10-3	☒		☐
		Comments:				
	25.	a.	If there are requirements regarding sterility, such as special	☐	☒	☐

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	• Any "No" answer will result in a "Refuse to Accept" decision. • Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.			**Yes**	**N/A**	**No**
			controls, in a device-specific regulation that are applicable to the device, the submission includes sterility information to establish that the submitter has followed the device-specific requirement. *Select "N/A" if there are no applicable requirements in a device-specific regulation. Select "No" if the submission does not include a rationale for any omitted information. Note that the adequacy of how such requirements have been addressed should be assessed during the substantive review.*			
		b.	If there is a device-specific guidance, other than a special controls guidance document, applicable to the device, the submission includes sterility information to establish that the submitter has addressed the recommendations or otherwise has met the applicable statutory or regulatory criteria through an alternative approach. *Select "N/A" if there is no applicable device-specific guidance. Select "No" if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how recommendations in a device-specific guidance have been addressed should be assessed during the substantive review.*		☒	
		c.	If there is a special controls document applicable to the device, the submission includes sterility information to establish that the submitter has complied with the particular mitigation measures set forth in the special controls document or uses alternative mitigation measures but provides a rationale to demonstrate that those alternative measures identified by the firm will provide at least an equivalent assurance of safety and effectiveness. *Select "N/A" if there is no applicable special controls document. Select "No" if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how mitigation measures in a*		X	

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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.					
	• Any "No" answer will result in a "Refuse to Accept" decision. • Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.			**Yes**	**N/A**	**No**
			special controls document have been addressed should be assessed during the substantive review.			
		Comments:				
F.	**Shelf Life**					
	26.	Proposed shelf life/ expiration date stated *Select "N/A" if the device is not provided sterile and the submitter states that storage conditions could not affect device safety or effectiveness.*		☐	☒	☐
		Comments:				
	27.	For sterile device, submission includes summary of methods used to establish that device sterility will remain substantially equivalent to that of the predicate through the proposed shelf life, or a rationale for why testing to establish shelf life is not applicable. *Select "N/A" if the device is not provided sterile.*		☐	☒	☐
		Comments:				
	28.	Submission includes summary of methods used to establish that device performance is not adversely affected by aging and therefore device performance will remain substantially equivalent to that of the predicate, or includes a rationale for why the storage conditions are not expected to affect device safety or effectiveness.		☒ p.10-3		☐
		Comments:				
G.	**Biocompatibility** *If in vitro diagnostic (IVD) device, select "N/A." The criteria in this section will be omitted from the checklist if "N/A" is selected.*				☐	
	Submission states that there: (*one of the below must be checked*) ☒ are Section 13					☐

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	• Any "No" answer will result in a "Refuse to Accept" decision. • Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.		**Yes**	**N/A**	**No**
	☐ are not direct or indirect (e.g., through fluid infusion) patient-contacting components. This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination. *If "are not" is selected, the biocompatibility-related criteria below are omitted from the checklist. If information regarding whether the device is patient-contacting is not provided, select "No."*				
	Comments:				
	29.	Submission includes list of patient-contacting device components and associated materials of construction, including identification of color additives, if present	☒ Section	13	☐
		Comments:			
	30.	Submission identifies contact classification (e.g., surface-contacting, less than 24 hour duration)	☒ Section	13	☐
		Comments:			
	31.	Biocompatibility assessment of patient-contacting components Submission includes: Test protocol (including identification and description of test article), methods, pass/fail criteria, and results provided for each completed test, OR a statement that biocompatibility testing is not needed with a rationale (e.g., materials and manufacturing/processing are identical to the predicate).	☒ Section	13	☐
		Comments:			
H.	**Software**				

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	• Any "No" answer will result in a "Refuse to Accept" decision. • Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.		**Yes**	**N/A**	**No**
	Submission states that the device: (*one of the below must be checked*) ☒ does Section 16 ☐ does not contain software/firmware. This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination. *If "does not" is selected, the software-related criterion is omitted from the checklist. If information regarding whether the device contains software is not provided, select "No."*				☐
	Comments:				
	32.	Submission includes a statement of software level of concern and rationale for the software level of concern	☒ Section 16		☐
		Comments:			
	33.	All applicable software documentation provided based on level of concern identified by the submitter, as described in Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, or the submission includes information to establish that the submitter has otherwise met the applicable statutory or regulatory criteria through an alternative approach (i.e., the submitter has identified an alternate approach with a rationale).	☒ Section 16 & App.D		☐
		Comments:			
I.	**EMC and Electrical Safety**				
	Submission states that the device: (*one of the below must be checked*) ☒ does Section 12 ☐ does not require EMC and Electrical Safety evaluation.				☐

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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.					
	• Any "No" answer will result in a "Refuse to Accept" decision. • Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.		**Yes**	**N/A**	**No**
	This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination. *If "does not" is selected, the EMC-related and Electrical Safety-related criteria below are omitted from the checklist. If information regarding whether the device requires EMC and Electrical Safety evaluation is not provided, select "No."*				
	Comments:				
	34.	Submission includes evaluation of electrical safety (e.g., per IEC 60601-1, or equivalent FDA-recognized standard, and if applicable, the device-specific standard), OR submission includes electrical safety evaluation using methods or standards that are not FDA-recognized and submission includes information to establish that the submitter has otherwise met the applicable statutory or regulatory criteria through this alternative approach (i.e., the submitter has identified alternate methods or standards with a rationale).	Section 12 &	☒	App.C	☐
		Comments:				
	35.	Submission includes evaluation of electromagnetic compatibility (e.g., per IEC 60601-1-2 or equivalent FDA-recognized standard and if applicable, the device-specific standard) OR submission includes electromagnetic compatibility evaluation using methods or standards that are not FDA-recognized and submission includes information to establish that the submitter has otherwise met the applicable statutory or regulatory criteria through this alternative approach (i.e., the submitter has identified alternate methods or standards with a rationale).	Section 12 &	☒	App.C	☐
		Comments:				

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	• Any "No" answer will result in a "Refuse to Accept" decision. • Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.			**Yes**	**N/A**	**No**
J.	**Performance Data – General** *If in vitro diagnostic (IVD) device, select "N/A." The criteria in this section will be omitted from the checklist if "N/A" is selected. Performance data criteria relating to IVD devices will be addressed in Section K.*				☐	
	Comments:					
	36.	Full test report is provided for each completed test. A full test report includes: objective of the test, description of the test methods and procedures, study endpoint(s), pre- defined pass/fail criteria, results summary, conclusions, and an explanation of how the data generated from the test supports a finding of substantial equivalence. *Full test reports provided for all completed tests/evaluations (e.g., bench evaluations, comparative performance tests, etc.). Select "N/A" if the submission does not include performance data.*		☒ Section 12	☐ & App	☐ C
		Comments:				
	37.	a.	If there are requirements regarding performance data, such as special controls, in a device-specific regulation that are applicable to the device, the submission includes performance data to establish that the submitter has followed the device-specific requirement. *Select "N/A" if there are no applicable requirements in a device-specific regulation. Select "No" if the submission does not include a rationale for any omitted information. Note that the adequacy of how such requirements have been addressed should be assessed during the substantive review.*	☐	☒	☐
		b.	If there is a device-specific guidance, other than a special controls guidance document, applicable to the device, the submission includes performance data to establish that the submitter has addressed the recommendations or otherwise has met the applicable statutory or regulatory criteria through an alternative	☐	☒	☐

Elements of a Complete Submission (RTA Items) (21 CFR 807.87 unless otherwise indicated) Submission should be designated RTA if not addressed						
Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.						
	• Any "No" answer will result in a "Refuse to Accept" decision. • Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.			**Yes**	**N/A**	**No**
			approach. *Select "N/A" if there is no applicable device-specific guidance. Select "No" if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how recommendations in a device-specific guidance have been addressed should be assessed during the substantive review.*			
		c.	If there is a special controls document applicable to the device, the submission includes performance data to establish that the submitter has complied with the particular mitigation measures set forth in the special controls document or uses alternative mitigation measures but provides a rationale to demonstrate that those alternative measures identified by the firm will provide at least an equivalent assurance of safety and effectiveness. *Select "N/A" if there is no applicable special controls document. Select "No" if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how mitigation measures in a special controls document have been addressed should be assessed during the substantive review.*		☐	☒	☐
		Comments:				
	38.	If literature is referenced in the submission, submission includes: *Select "N/A" if the submission does not reference literature. Note that the applicability of the referenced article to support a substantial equivalence finding should be assessed during the substantive review; only the presence of a discussion is required to support acceptance.*			☐	
		a.	Legible reprints or a summary of each article	App.F	☒	☐
		b.	Discussion of how each article is applicable to support the	App.E	☒	☐

Elements of a Complete Submission (RTA Items) **(21 CFR 807.87 unless otherwise indicated)** Submission should be designated RTA if not addressed						
Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.						
	• Any "No" answer will result in a "Refuse to Accept" decision. • Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.			**Yes**	**N/A**	**No**
			substantial equivalence of the subject device to the predicate.			
		Comments:				
	39.	For each completed nonclinical (i.e., animal) study conducted, *Select "N/A" if no animal study was conducted. Note that this section does not address biocompatibility evaluations, which are assessed in Section G of the checklist,*			☒	
		a.	Submission includes a study protocol which includes all elements as outlined in 21 CFR 58.120	☐		☐
		b.	Submission includes final study report which includes all elements outlined in 21 CFR 58.185	☐		☐
		c.	Submission contains a statement that the study was conducted in compliance with applicable requirements in the GLP regulation (21 CFR Part 58), or, if the study was not conducted in compliance with the GLP regulation, the submission explains why the noncompliance would not impact the validity of the study data provided to support a substantial equivalence determination.	☐		☐
		Comments:				
K.	**Performance Characteristics – In Vitro Diagnostic Devices Only (see also 21 CFR 809.10(b)(12))**					
	Submission indicates that device: (*one of the below must be checked*) ☐ is ☒ is not an in vitro diagnostic device (IVD). *If "is not" is selected, the performance data-related criteria below are omitted from the checklist.*					
	Comments:					

Elements of a Complete Submission (RTA Items) (21 CFR 807.87 unless otherwise indicated) Submission should be designated RTA if not addressed						
Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.						
	• Any "No" answer will result in a "Refuse to Accept" decision. • Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.			**Yes**	**N/A**	**No**
	40.	Submission includes the following studies, as appropriate for the device type, including associated protocol descriptions, study results and line data:				
		a.	Precision/reproducibility	☐	☐	☐
		b.	Accuracy (includes as appropriate linearity; calibrator or assay traceability; calibrator and/or assay stability protocol and acceptance criteria; assay cut-off; method comparison or comparison to clinical outcome; matrix comparison; and clinical reference range or cutoff.	☐	☐	☐
		c.	Sensitivity (detection limits, LoB, LoD, LoQ where relevant for the device type).	☐	☐	☐
		d.	Analytical specificity	☐	☐	☐
		Comments:				
	41.	a.	If there are requirements regarding performance data, such as special controls, in a device-specific regulation that are applicable to the device, the submission includes performance data to establish that the submitter has followed the device-specific requirement. *Select "N/A" if there are no applicable requirements in a device-specific regulation. Select "No" if the submission does not include a rationale for any omitted information. Note that the adequacy of how such requirements have been addressed should be assessed during the substantive review.*	☐	☐	☐
		b.	If there is a device-specific guidance, other than a special controls guidance document, applicable to the device, the submission includes performance data to establish that the submitter has addressed the recommendations or otherwise has met the	☐	☐	☐

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Elements of a Complete Submission (RTA Items) (21 CFR 807.87 unless otherwise indicated) Submission should be designated RTA if not addressed						
Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.						
	• Any "No" answer will result in a "Refuse to Accept" decision. • Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.			**Yes**	**N/A**	**No**
			applicable statutory or regulatory criteria through an alternative approach. *Select "N/A" if there is no applicable device-specific guidance. Select "No" if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how recommendations in a device-specific guidance have been addressed should be assessed during the substantive review.*			
		c.	If there is a special controls document applicable to the device, the submission includes performance data to establish that the submitter has complied with the particular mitigation measures set forth in the special controls document or uses alternative mitigation measures but provides a rationale to demonstrate that those alternative measures identified by the firm will provide at least an equivalent assurance of safety and effectiveness. *Select "N/A" if there is no applicable special controls document. Select "No" if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how mitigation measures in a special controls document have been addressed should be assessed during the substantive review.*	☐	☐	☐
		Comments:				

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Decision: Accept ___ Refuse to Accept ___

If Accept, notify applicant; if Refuse to Accept, notify applicant in writing and include a copy of this checklist.

Reviewer Signature: _____ Date: _____

Supervisory Signature: _____ Date: _____

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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510(k) Summary

Submitter:

Millennium Dental Technologies, Inc.
10945 South Street
Suite 306
Cerritos, California 90703
Telephone: (562) 860-2906
Fax: (562) 860-2949
Contact Person: David Harris, Chief Science Officer
Mobile: (510) 502-3345
Date Prepared: June 22, 2015

1. **Device Name:**

Trade Name:	PerioLase Nd:YAG Pulsed Dental Laser System
Common Name:	Nd:YAG Pulsed Dental Laser
Classification Name:	Laser surgical instrument for use in general and plastic surgery and in dermatology
Classification Regulation:	21 CFR 878.4810
Classification Panel:	General and Plastic Surgery
Device Class:	Class II
Product Code:	GEX

2. **Legally Marketed Predicate Device:**
   PerioLase, Millennium Dental Technologies, K030290

3. **Device Description:**
   PerioLase Nd:YAG Pulsed Dental Laser System (same as K010771, K014272, and K030290)

   The laser head consists of a flashlamp-pulsed Nd:YAG rod in an optical resonant cavity. The energy and the width of each laser pulse are determined by the size and shape of the current pulse through the flashlamp. The current pulse through the flashlamp is controlled by the flashlamp switching circuit. This circuit is based on a solid-state switch that sets the current level and pulse width according to the microprocessor controller. The rate at which the laser pulses are produced, the repetition rate or the pulses/second, is also determined by the microprocessor-controlled switching circuit. The output energy of each laser pulse is measured by

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the internal energy monitor. This value is compared to the energy setting by the microcontroller and adjustments are made if necessary.

The laser beam emitted from the laser head is coupled into a fiber-optic cable at the fiber port. The presence of the fiber-optic cable is detected by a sensor such that the laser will not fire if the fiber-optic cable is not in place. The laser aperture is at the distal tip of the fiber. The laser head is cooled by circulating water whose excess heat is removed by an air-water heat exchanger.

The operator controls the laser through the touch screen display. The microcontroller handles all of the logic required to set the energy levels, pulse widths, and repetition rates for the laser output, monitors the output pulses to assure proper output energy, monitors all of the interlocks and sensors, and checks for proper operation of the switches, power supplies, and cooling system. Proper operation of the microcontroller is checked by an independent watchdog microprocessor. The system is designed such that no single fault can result in a system failure.

All of the requirements of the laser safety standards of the CDRH as well as of the IEC 60825-1 standard are incorporated, including the remote interlock connector, the laser stop button, the key control, and the safety and manufacturers labels.

Wavelength	1.064 microns (1064 nm)
Pulse Energy	20 to 300 mJ
Pulse Width	100 µsec to 650 µsec
Repetition Rate	10 to 100 Hz
Average Power	6 Watts maximum
Laser Classification	Class IV

4. Intended Uses:

The PerioLase Nd:YAG Pulsed Dental Laser System is to provide the ability to perform intraoral soft tissue dental, general, oral maxillofacial, and cosmetic surgery. The PerioLase is intended for ablating, incising, excising, vaporization and coagulation of soft tissues using a contact fiber-optic delivery system. The device will be used in the following areas: general and cosmetic dentistry, otolaryngology, arthroscopy, gastroenterology, general surgery, dermatology and plastic surgery, neurosurgery, gynecology, urology, ophthalmology, and pulmonary surgery. The following are the oropharyngeal indications for use for which the device will be marketed:

Oropharyngeal

- Abscess incision and drainage
- Aphthous ulcers treatment
- Biopsies excision and incision
- Crown lengthening
- Hemostatic assistance
- Fibroma removal

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- Frenectomy
- Frenotomy
- Gingival incision and excision
- Gingivectomy
- Gingivoplasty
- Operculectomy
- Oral papillectomy
- Tissue retraction for impression
- Vestibuloplasty
- Selective ablation of enamel (first degree) caries
- Exposure of unerupted / partially erupted teeth
- Implant recovery
- Lesion (tumor) removal
- Leukoplakia
- Pulpotomy
- Pulpotomy as adjunct to root canal therapy
- Removal of filling material such as gutta-percha or resin as adjunct treatment during root canal retreatment
- Sulcular debridement (removal of diseased or inflamed soft tissue in the periodontal pocket) to improve clinical indices including gingival index, gingival bleeding index, probe depth, attachment level, and tooth mobility
- Laser-assisted new attachment procedure (cementum-mediated periodontal ligament new-attachment to the root surface in the absence of long junctional epithelium)
- Periodontal regeneration – true regeneration of the attachment apparatus (new cementum, new periodontal ligament, and new alveolar bone) on a previously diseased root surface when used specifically in the LANAP® Protocol

5. Summary of a Comparison of Technological Characteristics:

The comparison table provided in the Substantial Equivalence Comparison section of this submission establishes the basis for the determination of substantial equivalence of the PerioLase Nd:YAG Pulsed Dental Laser System to its named predicate device.

The PerioLase Nd:YAG Pulsed Dental Laser System has the identical wavelength, laser medium, beam delivery system type (optical fiber), laser activation method (footswitch), power source (conventional AC power), type of aiming beam and cooling system, and intended uses as its named predicate device.

The PerioLase Nd:YAG Pulsed Dental Laser System's power, pulse duration, energy per pulse, and repetition rate are identical to its named predicate device. There are no differences between the subject and predicate with respect to technology.

6. Nonclinical Performance Data:

The PerioLase Nd:YAG Pulsed Dental Laser System has been evaluated via verification and validation tests and inspections for conformance to applicable regulations and safety standards. Each PerioLase is tested for electrical safety and output characteristics to ensure it meets the design criteria for essential performance, its safety features and functions operate correctly, and it satisfies the

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performance requirements specified in 21 CFR 1010 and 21 CFR 1040. Representative data is presented in the Performance section and accompanying appendix of this submission.

7. **Clinical Performance Data:**

   Results of a prospective human histological study, included as an appendix to this application, provide evidence of true periodontal regeneration with new cementum, periodontal ligament, and alveolar bone on previously diseased root surfaces in patients treated nine months earlier with the LANAP® protocol using the PerioLase Nd:YAG Pulsed Dental Laser System.

8. **Conclusions:**

   The PerioLase Nd:YAG Pulsed Dental Laser System is substantially equivalent to the predicate device in technical characteristics, design features, operating principles, functional and performance characteristics, and for the intended uses in the stated medical specialties. The PerioLase is designed to comply with applicable federal and international safety and performance standards. Histologic data support the new clinical outcome claim. There are no new safety and effectiveness issues.

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Truthful and Accurate Statement

Section 510(k)
Premarket Notification

Truthful and Accuracy Statement
As required by 21 CFR 807.87(k)

I certify that, in my capacity as President of Millennium Dental Technologies, Inc., I believe to the best of my knowledge, that all data and information submitted in the premarket notification for the **PerioLase Nd:YAG Pulsed Dental Laser System** are truthful and accurate and that no material fact has been omitted.

Robert H. Gregg II, DDS

Robert H. Gregg II, DDS
for Millennium Dental Technologies, Inc.
Date: June 22, 2015
510(k) Number:

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Proposed Labeling

The conditions, purposes, and uses for which the device is intended (hazards, warnings, precautions, and contraindications) are provided in Sections 1, 5, and 6 of the Operator's Manual (See Appendix A of this submission) and in the previous PerioLase submissions (K010771, K014272, and K030290). There are no new safety and effectiveness issues.

Package Labels are shown in Section 1.3 of the Operator's Manual.

The intended use and oral and maxillofacial indications for use are described in Section 5 of the Operator's Manual and are identical to the ones shown in the Indications for Use form and in the 510(k) summary.

The Operator's Manual describes the device and its intended use and directions for use. Clinical guidelines and directions for use are specifically provided in Section 6.

The PerioLase does not include directions for the layperson as it qualifies for exemption as a prescription-only device per 21 CFR 801 Subpart D. Included in Section 1.1 of the Operator's Manual is the caution prescription use statement "Federal law restricts this device to sale by or on the order of a dentist or other licensed medical practitioner."

The labeling includes the name and place of business of the manufacturer, in compliance with 21 CFR 801.1. See Operator's Manual title page and Section 1.3.M.

The labeling establishes that the PerioLase Nd:YAG Pulsed Dental Laser System has followed the device-specific requirements and recommendations specified in applicable regulations and standards, as identified in the Operator's Manual. Mitigation measures applicable to laser devices (e.g., safety eyewear, posting of laser safety sign, plume control) are also described in the Operator's Manual. This information is consistent with the previous submissions for the PerioLase (K010771, K014272, and K030290). There are no new safety and effectiveness issues.

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Specifications

Narrative Description

Indications for Use

The PerioLase Nd:YAG Pulsed Dental Laser System is to provide the ability to perform intraoral soft tissue dental, general, oral maxillofacial, and cosmetic surgery. The PerioLase is intended for ablating, incising, excising, vaporization and coagulation of soft tissues using a contact fiber-optic delivery system. The device will be used in the following areas: general and cosmetic dentistry, otolaryngology, arthroscopy, gastroenterology, general surgery, dermatology and plastic surgery, neurosurgery, gynecology, urology, ophthalmology, and pulmonary general surgery. The following are the oropharyngeal indications for use for which the device will be marketed:

Oropharyngeal

- Abscess incision and drainage
- Aphthous ulcers treatment
- Biopsies excision and incision
- Crown lengthening
- Hemostatic assistance
- Fibroma removal
- Frenectomy
- Frenotomy
- Gingival incision and excision
- Gingivectomy
- Gingivoplasty
- Operculectomy
- Oral papillectomy
- Tissue retraction for impression
- Vestibuloplasty
- Selective ablation of enamel (first degree) caries
- Exposure of unerupted / partially erupted teeth
- Implant recovery
- Lesion (tumor) removal
- Leukoplakia
- Pulpotomy
- Pulpotomy as adjunct to root canal therapy
- Removal of filling material such as gutta-percha or resin as adjunct treatment during root canal retreatment
- Sulcular debridement (removal of diseased or inflamed soft tissue in the periodontal pocket) to improve clinical indices including gingival index, gingival bleeding index, probe depth, attachment level and tooth mobility
- Laser-assisted new attachment procedure (cementum-mediated periodontal ligament new-attachment to the root surface in the absence of long junctional epithelium)
- Periodontal regeneration – true regeneration of the attachment apparatus (new cementum, new periodontal ligament, and new alveolar bone) on a previously diseased root surface when used specifically in the LANAP® Protocol

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Principles of Operation (same as K010771, K014272, and K030290)
The PerioLase Nd:YAG Pulsed Dental Laser System is a solid-state, flashlamp-pumped, free-running, pulsed Nd:YAG laser that produces a pulsed beam of 1064-nm infrared light. Its power source is conventional AC power. The laser output is activated by a footswitch. The laser consists of two interconnected sections: The cabinet which houses the laser head, the power supply, the cooling system, and the microprocessor with control panel; and the fiber-optic delivery system with attached handpiece. The beam is transmitted to the treatment site by means of an optical fiber delivery system. The distal tip of the fiber is placed in contact with the target tissue. When the footswitch is depressed a shutter opens and laser emission enters the optical fiber. The light energy in the beam is transmitted to the target tissues. Localized decomposition of target tissue components, molecular phase changes, and rapid production of gases remove tissue through vaporization, cavitation, and spallation that are predominantly mechanical in nature. The process is highly localized within the beam path.

The following laser beam timing parameters can be independently selected:

- Pulse energy
- Pulse width
- Pulse repetition rate.

Recommended settings are provided in the Operator's Manual. Thorough training is mandatory before attempting a clinical procedure.

This information is consistent with the previous submissions for the PerioLase (K010771, K014272, and K030290) and Section 5 of the Operator's Manual. Professional Instructions for Use are provided in the previous submissions for the PerioLase (K010771, K014272, and K030290) and clinical guidelines are provided in Section 6 of the Operator's Manual. There are no new safety and effectiveness issues.

A list of components and accessories is provided in Section 2.1 of the Operator's Manual. The components and accessories have been previously cleared under the previous submissions for the PerioLase (KJ010771, K014272, and K030290). There are no new safety and effectiveness issues related to the components and accessories.

Physical Description (same as K010771, K014272, and K030290)

Labeled component drawings for the PerioLase Nd:YAG Pulsed Dental Laser System are provided in K010771 and in Section 1.3 of the Operator's Manual. Wiring schematics are provided in Appendix B of this submission. Drawings, illustrations, specifications, and dimensions are provided in Sections 1, 4.3, 7.1, and 10.1 of the Operator's Manual; physical dimensions and weight are summarized below:

Size	11" X 19" X 25" (27.9 x 48.2 x 63.5 cm)
Weight	45 lbs (20.4 kg)

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Sterilization Information

The PerioLase Nd:YAG Pulsed Dental Laser System and its accessories are provided non-sterile. User directions for sterilizing the patient-contacting components are included in the Operator's Manual. Sterilization information is consistent with the previous submissions for the PerioLase (K010771, K014272, and K030290). The patient-contacting components (i.e., silica glass optical fiber, anodized aluminum handpiece, and stainless steel cannula) of the PerioLase Nd:YAG Pulsed Dental Laser System are identical to the fiber, handpiece, and cannula of the predicate PerioLase Dental Laser System as it was cleared in 510(k) K010771, clearance date November 27, 2001, in formulation, processing, and sterilization, and no other chemicals have been added (e.g., plasticizers, fillers, color additives, cleaning agents, mold release agents, etc.). The processing and sterilization of these components are also identical to the predicate PerioLase Nd:YAG Pulsed Dental Laser System cleared in K010771. There are no new safety and effectiveness issues.

Specific information related to sterilization is provided in the Operator's Manual:

- Section 2.1 indicates that none of the components or accessories is provided sterile.
- Sections 3.1.A and 3.5 identify the accessories that are end user sterilized.
- Reusable accessories are identified and cleaning and disinfection instructions are provided in Sections 1.1, 2.3, 3.1, 3.2, 3.5, 4.1, 4.2, 6, 7.1, 7.3, and 8.2.
- Sterilization methods, parameters, and instructions are provided in Section 7.
- A list of packaging and packaging contents provided in Section 2.1.

Device Aging

There are no new safety and effectiveness issues related to device aging. Storage conditions are not expected to affect device safety or effectiveness of the PerioLase Nd:YAG Pulsed Dental Laser System, providing the environmental conditions specified in the Operator's Manual are complied with. Since the first PerioLase was shipped more than 13 years ago, Millennium Dental Technologies, Inc., has carefully tracked, but has no evidence of, any complaints traceable to disuse for any length of time.

Normal operating parameters are internally monitored upon laser startup and continuously during operation to help ensure safe and effective instrument operating conditions are in effect and are being maintained. If the system detects a problem, the laser is designed to fail in a safe mode, protecting the internal components, the user, and the patient. In that situation, the laser will not operate, an error code is displayed on the touch screen, and the user is advised to contact a qualified service representative. Further, as described in the Operator's Manual, the PerioLase has a built-in power meter that enables the user to confirm the laser power being emitted at the fiber tip with the power level being displayed on the touch screen.

The optional wireless footswitch is equipped with a battery-operated transmitter. The typical battery life is (b)(4) When insufficient battery power remains in the transmitter, the wireless footswitch will no longer operate. In this circumstance, the standard wired footswitch can be used.

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Substantial Equivalence Comparison

Summary of a Comparison of Technological Characteristics

The table on the following pages compares the PerioLase Nd:YAG Pulsed Dental Laser System to the predicate device with respect to technological characteristics and indications for use, providing more detailed information regarding the basis for the determination of substantial equivalence.

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Summary Table of a Comparison of Technological Characteristics

Characteristic	Millennium PerioLase (Current)	Millennium PerioLase K030290 7/26/04
Product Code Regulation	General & Plastic Surgery GEX, 21 CFR 878.4810	General & Plastic Surgery GEX, 21 CFR 878-4810
Intended Use	Intended for ablating, incising, excising, vaporizing, and coagulating soft tissues	Intended for ablating, incising, excising, vaporizing, and coagulating soft tissues
Wavelength	1064 nm	1064 nm
Power Watts	6W	6W
Pulse Duration (µsec)	100, 150, 250, 350, 450, 550, 650	100, 150, 250, 350, 450, 550, 650
Energy per pulse (mJ)	20-300	20-300
Output Mode	Pulsed, multi-mode	Pulsed, multi-mode
Repetition Rate	10-100 Hz	10-100 Hz
Laser Medium	Flashlamp-pumped, solid-state laser rod	Flashlamp-pumped, solid state laser rod
User Interface	Touch screen control panel	Touch screen control panel
Laser Activation	Footswitch	Footswitch
Beam Delivery	Fiber Optic	Fiber Optic
Cooling	Air-cooled (internal water loop)	Air-cooled (internal water loop)

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Characteristic	Millennium PerioLase (Current)	Millennium PerioLase K030290 7/26/04
Indications for Use Statement	Intended Uses of the Device: The PerioLase Nd:YAG Pulsed Dental Laser System is to provide the ability to perform intraoral soft tissue dental, general, oral maxillofacial, and cosmetic surgery. The PerioLase is intended for ablating, incising, excising, vaporization and coagulation of soft tissues using a contact fiber-optic delivery system. The device will be used in the following areas: general and cosmetic dentistry, otolaryngology, arthroscopy, gastroenterology, general surgery, dermatology & plastic surgery, neurosurgery, gynecology, urology, ophthalmology, and pulmonary surgery.	Intended Use(s) of the Device: The PerioLase Nd:YAG Pulsed Dental Laser System is to provide the ability to perform intraoral soft tissue dental, general, oral maxillofacial, and cosmetic surgery. The PerioLase is intended for ablating, incising, excising, vaporization and coagulation of soft tissues using a contact fiber-optic delivery system. The device will be used in the following areas: general and cosmetic dentistry, otolaryngology, arthroscopy, gastroenterology, general surgery, dermatology & plastic surgery, neurosurgery, gynecology, urology, ophthalmology, and pulmonary surgery.
Oropharyngeal / Dental Surgery Indications for Use	Intended use: The following are the oropharyngeal indications for use for which the device will be marketed: • Abscess incision and drainage • Aphthous ulcers treatment • Biopsies excision and incision • Crown lengthening • Hemostatic assistance • Fibroma removal • Frenectomy • Frenotomy • Gingival incision and excision • Gingivectomy • Gingivoplasty • Operculectomy • Oral Papillectomy • Tissue retraction for impression • Vestibuloplasty • Selective ablation of enamel (first degree) caries • Exposure of unerupted / partially erupted teeth • Implant recovery • Lesion (tumor) removal • Leukoplakia • Pulpotomy • Pulpotomy as adjunct to root canal therapy • Removal of filling material such as gutta-percha or resin as adjunct treatment during root canal retreatment • Sulcular debridement (removal of diseased or inflamed soft tissue in the periodontal pocket) to improve clinical indices including gingival index, gingival bleeding index, probe depth, attachment level and tooth mobility • Laser-assisted new attachment procedure (cementum-mediated periodontal ligament new-attachment to the root surface in the absence of long junctional epithelium) • Periodontal regeneration – true regeneration of the attachment apparatus (new cementum, new periodontal ligament, and new alveolar bone) on a previously diseased root surface when used specifically in the LANAP® Protocol	Intended use: The following are the oropharyngeal indications for use for which the device will be marketed: • Abscess Incision and Drainage • Aphthous ulcers treatment • Biopsies excision and incision • Crown lengthening • Hemostatic assistance • Fibroma removal • Frenectomy • Frenotomy • Gingival Incision and Excision • Gingivectomy • Gingivoplasty • Operculectomy • Oral Papillectomy • Tissue retraction for impression • Vestibuloplasty • Selective ablation of enamel (first degree) caries • Exposure of unerupted / partially erupted teeth • Implant recovery • Lesion (tumor) removal • Leukoplakia • Pulpotomy • Pulpotomy as adjunct to root canal therapy • Removal of filling material such as gutta-percha or resin as adjunct treatment during root canal retreatment • Sulcular debridement (removal of diseased or inflamed soft tissue in the periodontal pocket) to improve clinical indices including gingival index, gingival bleeding index, probe depth, attachment level and tooth mobility • Laser-assisted new attachment procedure (cementum-mediated periodontal ligament new-attachment to the root surface in the absence of long junctional epithelium)

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The named devices are prescription-only Class II medical devices, intended to be used in professional medical and dental facilities. They are AC-powered devices that deliver pulsed 1064-nm Nd:YAG laser energy of varying pulse durations, repetition rates, and energy levels via fiber-optic delivery system. User interfaces (i.e., control panels) are identical and the devices are activated by means of a footswitch. Cooling systems are of identical design. The devices are supplied non-sterile and directions for end user sterilization procedures are identical, and must provide biocompatibility assessment of patient-contacting components (i.e., optical fiber, cannula, and handpiece).

The named devices are governed by the same regulation numbers (21 CFR 878.4810, 21 CFR 1040.10 and 1040.11), have the same classification product code (GEX), abide by the same U.S. FDA Guidance Document (Guidance on the Content and Organization of a Premarket Notification for a Medical Laser (Draft), June 1995), and the same consensus standards for medical electrical equipment (e.g., IEC 60601-1) and laser devices (e.g., IEC 60825-1).

The named devices feature the same intended use and the same indications for use. (The submitted device includes a new clinical outcome claim.) Their target population (human patients with no restrictions on age) and anatomical sites, as determined by the named medical specialties, are identical. Having the same laser wavelength emission (i.e., 1064-nm Nd:YAG), they provide the same interaction with the target tissue.

The named devices incorporate specific laser safety features (e.g., key control, laser emission indicator, laser stop button, remote interlock connector, fiber sensor, protective housing, safety interlocks, location of controls, power display, manual reset, current leakage protection, system time-out) and specify identical eye protection for operator, patient, and all personnel in the operating area.

In summary, the PerioLase Nd:YAG Pulsed Dental Laser System has technical characteristics and tissue effects that are identical to the predicate device. There are no new safety and effectiveness issues.

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Performance

The PerioLase Nd:YAG Pulsed Dental Laser System is substantially equivalent to the predicate device in emission wavelength, control parameters, relative output power, delivery system, and physical size. Each PerioLase is tested for electrical safety and output characteristics to ensure it meets the design criteria for essential performance, its safety features and functions operate correctly, and it satisfies the performance requirements specified in 21 CFR 1010 and 21 CFR 1040. There are no new safety and effectiveness issues.

The PerioLase Nd:YAG Pulsed Dental Laser System has been evaluated via verification and validation tests and inspections for conformance to applicable safety standards and regulations as noted below.

IEC 60601-1. Medical Electrical Equipment – Part 1: General Requirements for Safety

IEC 60601-1-1. Medical Electrical Equipment – Part 1-1: General Requirements for Safety – Collateral Standard: Safety Requirements for Medical Electrical Systems

IEC 60601-1-2. Medical Electrical Equipment – Part 1-2: General Requirements for Basic Safety and Essential Performance – Collateral Standard: Electromagnetic Compatibility – Requirements and Tests

IEC 60601-1-4. Medical Electrical Equipment – Part 1-4: General Requirements for Safety – Collateral Standard: Programmable Electrical Medical Systems

IEC 60601-2-22. Medical Electrical Equipment – Part 2: Particular Requirements for the Safety of Diagnostic and Therapeutic Laser Equipment

IEC 60825-1. Safety of Laser Products – Part 1: Equipment Classification, Requirements and User's Guide

21 CFR 1040 Performance Standards for Light-Emitting Products.
Section 1040.10 Laser Products
Section 1040.11 Specific Purpose Laser Products

Representative test reports appear in Appendix C of this submission along with their respective objectives; methodologies, procedures, and parameters used; endpoints and pass/fail criteria; results summary and conclusions. Passing results confirm compliance with the applicable standards and support the finding of substantial equivalence to the PerioLase Nd:YAG Pulsed Dental Laser System previously cleared under K010771, K014272, and K030290.

Electrical
The PerioLase Nd:YAG Pulsed Dental Laser System passed electrical safety testing in accordance with requirements for medical electrical equipment.

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Electromagnetic Compatibility
The PerioLase Nd:YAG Pulsed Dental Laser System passed electromagnetic compatibility testing to meet requirements for medical electrical devices.

Software
Verification testing was conducted on the PerioLase Nd:YAG Pulsed Dental Laser System software. All tests with respect to stated pass/fail criteria were completed successfully, confirming the device and software to be appropriate for its intended use.

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Biocompatibility

Patient-contacting device components of the PerioLase Nd:YAG Pulsed Dental Laser System are the beam delivery system, consisting of a (b)(4) optical fiber with a (b)(4) and (b)(4)

Body contact classification: Surface
Duration of patient contact classification: Limited

Biocompatibility testing is not needed as th (b)(4) optical fiber, (b)(4) handpiece, and (b)(4) of the PerioLase Nd:YAG Pulsed Dental Laser System are identical to the fiber, handpiece, and cannula of the predicate PerioLase Nd:YAG Pulsed Dental Laser System as it was cleared in 510(k) K010771, clearance date November 27, 2001, in formulation, processing, and sterilization, and no other chemicals have been added (e.g., plasticizers, fillers, color additives, cleaning agents, mold release agents, etc.). The processing and sterilization of these components are also identical to the predicate PerioLase Nd:YAG Pulsed Dental Laser System cleared in K010771. There are no new safety and effectiveness issues.

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Design Controls

Procedures and policies related to design controls are defined within the Quality System of Millennium Dental Technologies, Inc. This Quality System was in effect when the PerioLase Nd:YAG Pulsed Dental Laser System was cleared under the previous PerioLase submissions, K010771, K014272, and K030290. There are no new safety and effectiveness issues.

Specifically, the Quality System defines the control process for product design to ensure that specified design requirements are met. Included are procedures that address the design history file, design input, design output, design review, device master record (i.e., transfer of device design to production specifications), specification, risk analysis, process and design validation (including software validation) to confirm that the final design meets the defined user needs and intended use of the device, verification, and the process for controlling design changes through the Engineering Change Order process and Document Control process.

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Radiation Emitting Products

In compliance with required regulations and guidance documents, Millennium Dental Technologies, Inc., has a defined policy for control and retention of documentation as an established component of its Quality System. Among the documents maintained are results of tests for compliance with applicable radiation safety performance standards, certifications of compliance, tracking of life testing and monitoring for effects of product disuse and storage over time, and tracking distribution of products to permit tracing in the event of a recall. The Quality System also defines procedures for postmarket surveillance and vigilance, and for reporting of accidental radiation occurrences or product defects to the FDA.

This Quality System was in effect when the PerioLase Nd:YAG Pulsed Dental Laser System was cleared under the previous PerioLase submissions, K010771, K014272, and K030290. Refer also to the Performance testing results in Section 12 of this submission that describes compliance with applicable FDA performance standards. There are no new safety and effectiveness issues.

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Software

The software for the PerioLase Nd:YAG Pulsed Dental Laser System was cleared under the previous PerioLase submissions, K010771, K014272, and K030290. There are no new safety and effectiveness issues.

During the design effort of the PerioLase Nd:YAG Pulsed Dental Laser System, all reasonable steps were taken to assure that hazards associated with the device were minimized. A Failure Modes and Effects Analysis (FMEA) of potential component failure conditions, effects, severity levels, and countermeasures was used to minimize the effects of failures.

Numerous documents were used as guidelines during the development of the FMEA analysis, including:

- EN 60601 Medical Laser Equipment
- EN 60825 Safety of Laser Products
- EN 61000 EMC.

Analysis of the software-related aspects of the FMEA analysis indicated a minor level of concern for the software, as failure of the system controller or touchscreen controller results in an inoperable system and laser emission is not allowed.

See Appendix D of this submission for documents related to FMEA and software requirements, design, and validation:

- Failure Modes and Effects Analysis (FMEA)
- Software Requirements Specification (SRS)
- Software Design Description (SDD)
- Software Validation Test Specification (SVTS).

Included in the documentation in either paragraph or tabular format are:

- an overview of the device features that are controlled by software and the intended operational environment (SRS);
- software description, programming language, and hardware platform (SDD);
- description of identified hardware and software hazards, including severity assessment, countermeasures and mitigations (FMEA);
- functional requirements (SRS);
- software design description (SDD);
- traceability matrix (SVTS);
- software validation procedures and results (SVTS);
- controller and display software version and date (SVTS).

Software validation testing (including initialization tests, standby mode tests, set up mode tests, service mode 1 and 2 tests, ready mode tests, firing mode tests, procedure screen tests, print screen tests, power screen display screen tests) was completed and all tested parameters passed (see SVTS document). The software documentation supports all performance and safety claims.

Displays of information, prompts, and check and error codes are described in detail in the Operator's Manual (see Appendix A of this submission).

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Standards

The PerioLase is designed to meet the applicable consensus standards identified below. Refer also to the accompanying completed forms (Form 3654). Representative test reports appear in Appendix C of this submission. Results of performance testing confirm comformity to the standards named in the test reports. There are no new safety and effectiveness issues.

- IEC 60601-1:1988 + A1:1991 + A:2 1995. Medical Electrical Equipment – Part 1: General Requirements for Safety
- IEC 60601-1-1 Edition 2.0 (2000). Medical Electrical Equipment – Part 1-1: General Requirements for Safety – Collateral Standard: Safety Requirements for Medical Electrical Systems
- IEC 60601-1-2 Edition 3.0 (2007). Medical Electrical Equipment – Part 1-2: General Requirements for Basic Safety and Essential Performance – Collateral Standard: Electromagnetic Compatibility – Requirements and Tests
- IEC 60601-1-4 Edition 1.1 Consolidated with Amendment 1 (2000-04). Medical Electrical Equipment – Part 1-4: General Requirements for Safety – Collateral Standard: Programmable Electrical Medical Systems
- IEC 60601-2-22 Edition 2.0 (1995). Medical Electrical Equipment – Part 2: Particular Requirements for the Safety of Diagnostic and Therapeutic Laser Equipment
- IEC 60825-1 Edition 1.0 (1993). Safety of Laser Products – Part 1: Equipment Classification, Requirements and User's Guide

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PERIOLASE® MVP-7™ DENTAL LASER

OPERATOR'S MANUAL

MILLENNIUM DENTAL TECHNOLOGIES, INC.

10945 South Street, Suite 104-A,
Cerritos, CA 90703

Toll Free Phone: 1-888-49-LASER
Service/Repair: 1-888-495-2799
Phone: 562-860-2908
FAX 562-860-2429
www.millenniumdental.com

MDT/IALD COMPANY CONFIDENTIAL

Doc. No: 06-01-001 Rev: S.1 Draft May 2015

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Millennium Dental Technologies reserves the right to make changes to product descriptions and specifications without notice.

With respect to any pharmaceutical products identified in this manual, clinicians are advised to check the most current information provided by the manufacturer of each product to verify the recommended dose, the duration of administration, and contraindications.

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1. Safety and Performance

1.1 Warnings and Cautions

WARNING: The PerioLase® MVP-7™ Dental Laser is a Class IV laser. Laser light is emitted from the end of the fiber-optic cable. Avoid eye exposure to direct or scattered radiation without protective eyewear. The dentist, patient, and all others in the room must wear protective eyewear that has an optical density of 4.0 or greater to the wavelength of the free-running (FR) Nd:YAG laser, which emits infrared light at 1,064 nanometers (nm).

WARNING: Protect the fiber-optic cable from damage or breaking. Damage to the fiber could cause release of laser light and potentially harm the patient or user. The red aiming beam passes down the fiber at the same time as the laser energy. It also provides a method of checking the integrity of the fiber. If the red aiming beam becomes absent or reduced, it may indicate a damaged fiber.

WARNING: Do not remove the outer cover of the laser head. Removal of the laser head housing exposes one to the dangerous voltages and laser light contained in the laser head housing.

WARNING: Exposing the laser to temperatures below 10º C (50º F) and above 40º C (104º F) will cause damage to the laser. DO NOT FREEZE. Do not expose the laser to extreme temperatures.

CAUTION: Use of controls or adjustments or performance of procedures other than those specified herein may result in hazardous exposure.

CAUTION: Laser plume may contain viable tissue particulates. Remove plume with a high-volume evacuation system.

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CAUTION: The use of flammable anesthetics should be avoided. The solvents of adhesives and flammable solutions used for cleaning and disinfecting should be allowed to evaporate completely before using the laser.

CAUTION: To prevent inadvertent operation, switch the key to the OFF position and remove the key when not in use.

RxOnly

CAUTION: Federal law restricts this device to sale by or on the order of a dentist or physician or other licensed medical practitioner.

1.2 Laser Safety Eye Protection

1.2.A Operator Eye Protection

All personnel in the operating area must wear the proper laser safety protective eyewear to prevent accidental eye damage.

Three pairs of 1064-nm safety glasses are supplied with the PerioLase® Periodontal Package™ – one each for use by the operator, the assistant, and the patient. Additional pairs of safety glasses are available from Millennium Dental Technologies, Inc. (Millennium).

1.2.B Patient Eye Protection

The patient must wear laser safety glasses or goggles during treatment.

1.3 Laser Safety Features

The PerioLase® MVP-7™ complies with all performance standards as specified in 21 CFR 1040.10 and 1040.11 as administered by the Center for Devices and Radiological Health (CDRH) of the U.S. Food and Drug Administration (FDA). Refer to Figures 1 and 2 for locations of specific safety features on the laser.

1.3.A Key Control

The laser system can only be turned on with the proper key. The key cannot be removed except in the OFF position. The laser will operate only with the key in place and turned to the ON position.

1.3.B Laser Emission Indicator

The Laser Emission Indicator is located on the top center of the control panel. When the Laser Emission Indicator is illuminated, it signals that the system is emitting laser radiation by flashing the word "**LASER**."

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1.3.C Laser Stop

A red "**LASER STOP**" button is provided on the front of the console. Laser output is terminated when this button is pressed.

1.3.D Remote Interlock Connector

The control system will prevent laser emission unless electrical continuity is made across the contacts of the remote interlock connector. The remote interlock plug, as supplied, has a shorting contact, which will allow the instrument to operate when it is plugged in. To set up a remote safety interlock, such as on the treatment room door, please contact Millennium if assistance is required.

1.3.E FiberFlex™ Fiber Sensor

A non-contact sensor detects the presence of the beam-delivery FiberFlex™ fiber. The laser will not enter the **READY** mode and cannot fire if the FiberFlex™ fiber is not installed. Failure of the sensor will not allow the laser to fire.

1.3.F Protective Housing

The laser head system has a protective housing that prevents unintended access to laser radiation. The user does not have to perform maintenance or service operations inside the protective covers. Only an authorized service representative should open the protective housing.

1.3.G Safety Interlocks

No sections of the protective laser head housing can be opened without special tools. Removal of the outside chassis cover does not permit access to laser radiation and there are no interlocks provided.

1.3.H Location of Controls

All controls are located on the control panel for safe access during system operation, except for the "**LASER STOP**" button, the key switch, and the printer paper advance that are located on the front of the console and AC power on/off switch that is located on the back of the laser.

1.3.I Power Display

The average power, displayed in Watts (W), is shown in the LCD at the center of the control panel. The average power is the product of the energy per pulse (joules) and the pulse repetition rate (pulses per second or hertz).

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1.3.J Manual Reset

If laser emission is interrupted (e.g., opening the remote interlock circuit) the laser will turn off and the system will go into **STANDBY** mode. To resume treatment, press the "**READY**" button.

1.3.K Leakage Protection

The system meets all of the current leakage requirements of the IEC 60601-1 Clause 19 standard.

1.3.L System Time-Out

If the system is in **READY** mode and it is not used for a period of 5 minutes, it will go into **STANDBY** mode. To resume operation, press the "**READY**" button.

1.3.M Labels

The following labels are affixed to the device as shown in the following drawings:

Manufacturer's Certification and Identification Label

Millennium Dental Technologies, Inc.
10945 South Street, Suite 104-A
Cerritos, CA 90703

Model:	**PerioLase MVP-7** Nd:YAG dental laser
S/N:	**PL XXXXX**
Manufactured:	**DD MM YYYY**
Rated:	110 - 240 V~, 8A, 50/60 Hz

THIS PRODUCT COMPLIES WITH

21CFR 1040.10 AND 1040.11

MADE IN USA

Remote Interlock Label:

REMOTE INTERLOCK

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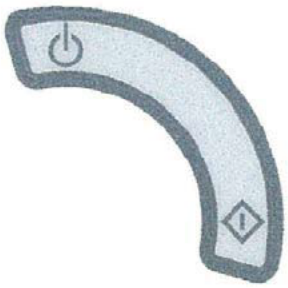
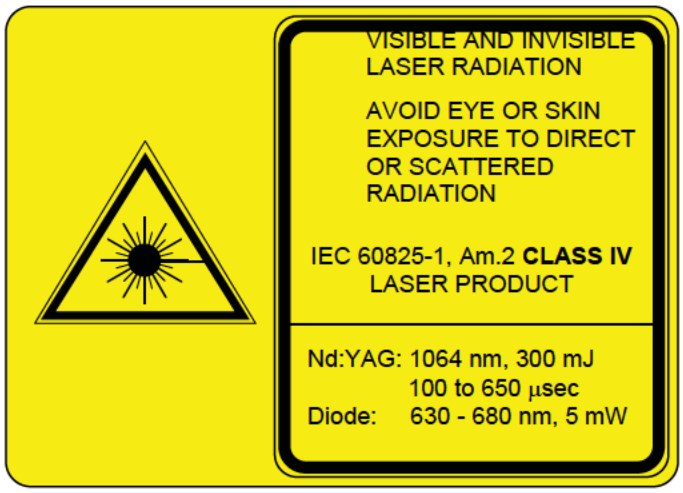
Laser Aperture Label:

Key Switch Label:



Laser Stop Label:

Laser Warning Logotype & Label:



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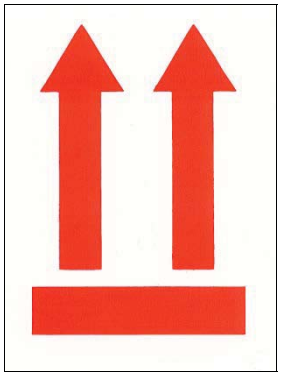
Packaging Labels

This Side Up Label:



This Side Up/Fragile/Handle With Care Label

Do Not Freeze Label:

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Fragile Label:

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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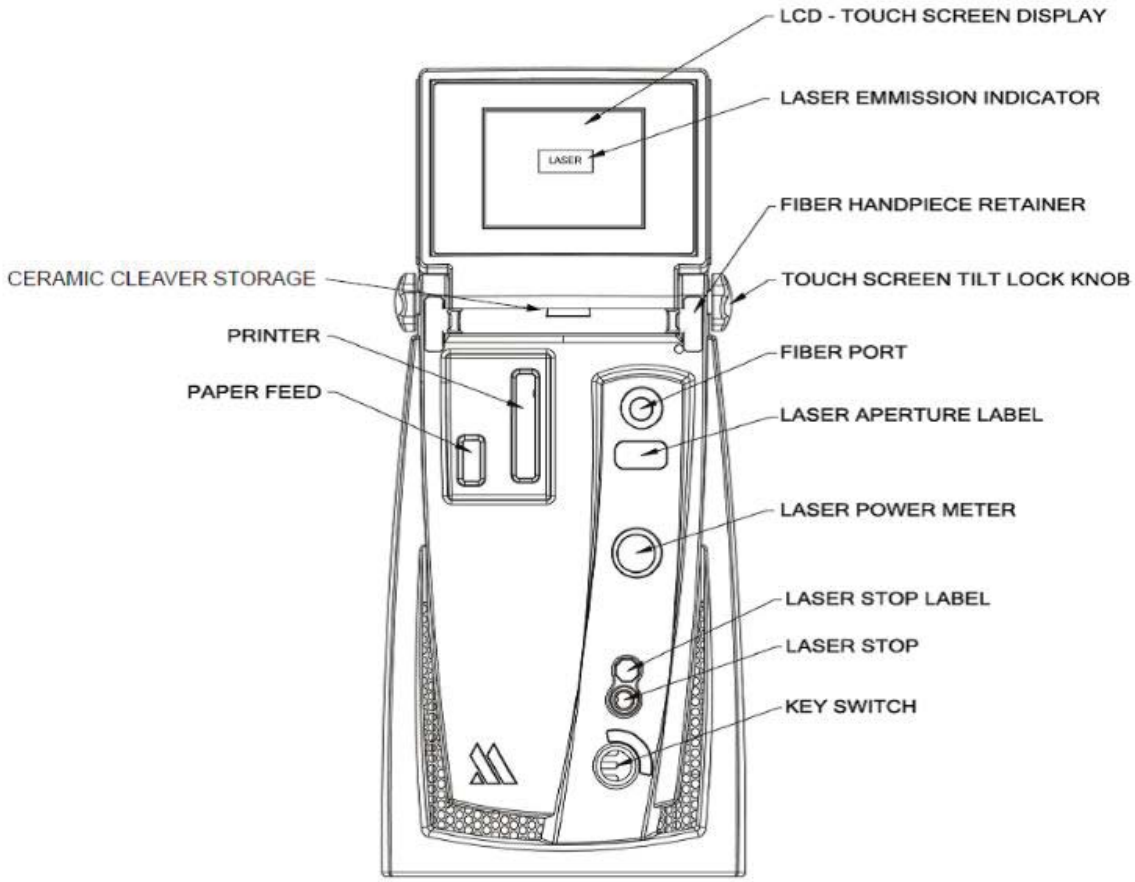

Figure 1: Front View

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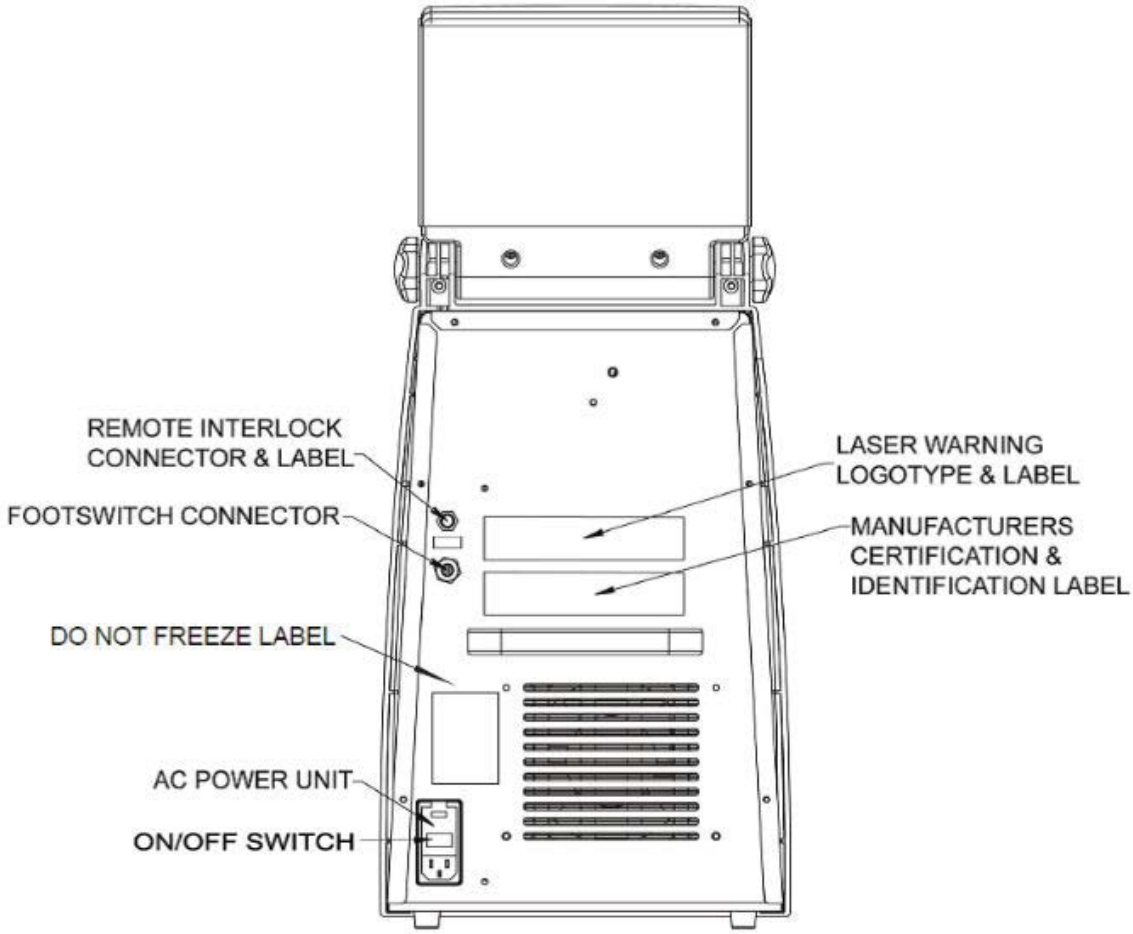

Figure 2: Rear View

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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2. Setup

2.1 Packaging and Contents

The PerioLase® MVP-7™ Nd:YAG Pulsed Dental Laser System includes the following components. None of the components are provided sterile.

1 Shipping Box with custom-fit foam inserts for the laser console

1 Shipping Box with custom-fit foam inserts for the laser cart

1 PerioLase® MVP-7™ Dental Laser operator's manual

1 Printer loading instructions

1 Certificate of warranty

1 PerioLase® MVP-7™ laser console

1 PerioLase® MVP-7™ laser cart

4 Cart wing bolts

2 360-micron FiberFlex™ fibers

1 Short (5-3/4") TrueFlex™ handpiece

1 Long (6-3/4") TrueFlex™ handpiece

2 TrueFlex™ Cannulae

1 Fiber stripping tool

3 Ceramic fiber cleavers

3 Cannula brushes

1 Standard safety glasses (large)

1 Standard safety glasses (regular)

1 Patient safety goggles

1 Laser safety sign

1 Touch screen cover

1 Power cord

2 Laser keys

1 Interlock plug

1 Wired footswitch

1 Wireless footswitch with 3 AA batteries (optional)

1 Wireless footswitch operator's manual (included with available wireless footswitch)

1 Printer paper roll (preloaded)

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1 Set LANAP® protocol hand instruments:

- 1 Sub 0 Curette DE H/H
- 1 Curette 13/14 H/H
- 1 File Perio Hirschfeld 3/7
- 1 Perio DE Hirschfeld 5/11 Bone & Root File
- 1 Curette 11/12 H/H Bone & Root File
- 1 Curette Morse 0/00 HH
- 1 Curette Mini 11/12 H/H

2.2 Unpacking

Save all packing material for service shipments.

Note: Unpacking instructions for your shipping box are included as an insert in the shipment.

2.3 Assembly for Use

CAUTION: Cooling air is drawn in through the openings on the front of the instrument, and blows out from the vents at the rear. Avoid blocking the air vents at the front or at the back of the PerioLase® when locating the instrument.

2.3.A Remove the Accessory box from the cart's shipping box. Remove the laser and the laser cart from their respective shipping boxes. Remove the footswitch and power cord from the drawer in the laser cart.

2.3.B Remove the drawer from the laser cart by pulling it out as far as it will go, depress the metal lock tabs on each side of the drawer at the runner as you continue to pull the drawer forward. This will allow the drawer to come completely out.

2.3.C Align the laser rubber feet on top of the cap nuts on the top of the laser cart. This will align the screw holes for securing the laser to the cart.

2.3.D Near each rubber foot of the laser is a hole in the top of the cart. Locate this hole from the inside of the cart. Place one of the finger screws through each of the holes up into the laser. When it is aligned properly, the screw will go in easily. Tighten each screw as tight as you are able with your fingers only.

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2.3.E Replace the cart drawer in the cart, making sure that the drawer runners are inserted properly into their counterparts. The drawer should close completely.

2.3.F Install the remote interlock plug into the jack at the rear of the instrument. (See Figure 2 on page 1-9 for location.)

2.3.G Connect the footswitch to the fitting at the rear of the instrument. Align the slot in the connector on the cable with the key in the connector on the instrument. Secure the connectors by turning the bayonet-style ring clockwise until it locks. (See Figure 2 on page 1-9 for location.)

An optional wireless footswitch is available. Refer to the separate "Infrared Wireless Footswitch Operator's Manual" that is provided with the optional wireless footswitch for instructions for use.

2.3.H Raise the touch-screen display to a visible angle by loosening the knob on either side of the display. After properly orienting the display screen, fully tighten the knobs. Remove the protective cover and store it by sliding it onto the back of the touch-screen display.

2.3.I Connect the power cord to the AC inlet at the rear of the instrument. (See Figure 2 on page 1-9 for location.) Plug the cord into a 120 V~ outlet. *Note: Millennium Dental Technologies, Inc., recommends the use of a power surge protector.*

2.3.J Set the main on-off electrical power switch, located just above the power line cord connector, to the ON position. The internal power supply cooling fan will start running.

2.3.K Install the FiberFlex™ fiber, remove the protective cap from the fiber and the laser output (fiberport) [these protective caps need to be kept and both replaced when the fiber is removed for any period of time], align the connector end with the laser output (fiberport) (see Figure 1 on page 1-8 for location) and slide into position until fully seated. Tighten the metal sleeve by turning the sleeve clockwise until it is finger-tight. It will be easy to tighten and remove if properly installed. (For information about the FiberFlex™ fiber optic, see Chapter 3.)

2.3.L Insert one of the keys into the key switch at the front of the instrument. Turn the key to the start position. The touch-screen display panel will illuminate. (See Figure 1 on page 1-8 for location.)
Note: Millennium Dental Technologies, Inc., recommends storing the extra key in a separate location.

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2.3.M After the display panel shows the **MILLENNIUM** title screen, it will go through its control start-up procedure, and then show the **MAIN** operating screen.

2.3.N On the **MAIN** operating screen in the lower left corner of the touch screen is the "**SETUP**" button. Touch this "**SETUP**" button and it will take you into the **SETUP** screen where three buttons will appear in the middle of the screen. The bottom button is the "**CONTROL PANEL**." Touch this button. The screen will change to the **CONTROL PANEL** screen.

2.3.O On the **CONTROL PANEL** screen, you will find on the bottom line in the center of the screen the word "**AIMING** (followed by a number 0 to 5)." Below this phrase are two buttons. (Touch the "**+aim**" or "**-aim**" button to achieve the desired aiming beam intensity.) When you are satisfied with the intensity of the aiming beam, go to the next step.

2.3.P To the left of the Aiming beam buttons is the contrast of the screen buttons listed as "**Contr** (followed by a number)." Below this phrase are two buttons. (Touch the "**+con**" or "**-con**" button to achieve the desired contrast to the screen intensity.) Somewhere in the mid 30s is the optimum contrast but it is OK to increase or decrease the contrast to find the contrast that best suits your desire. Once the desired contrast has been achieved, go to the next step.

2.3.Q Check the date and time on the screen and adjust as needed for your area and time zone. This is done in the same manner as the buttons used for changing the Aiming beam and Contrast screen. When this is complete, press the "**MAIN**" button. This will take you back to the **MAIN MENU** screen.

2.3.R On the **MAIN** operating screen in the lower left corner of the touch screen is the "**SETUP**" button. Touch this "**SETUP**" button and it will take you to the **SETUP** screen where three buttons will appear in the middle of the screen. This time touch the "**USER INFO**" button in the center. The **USER INFORMATION** screen will appear with buttons to edit three users' information. Touch the top button marked "**EDIT USER 1**" and this will take you to a screen with an alphanumeric setup that allows you to type in your last name. Do this now. When you are satisfied, press "**ENTER**" on the bottom left of the screen. The next screen allows you to type in your first name. Do this now. When you are satisfied, press "**ENTER**." The next screen allows you to type in a code or special information you may want to identify yourself – or you may leave it blank if desired. Do this now. When you are satisfied, press "**ENTER**." You will return to the **MAIN** screen.

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2.3.S Your laser is now ready to work for you. When you are comfortable with the rest of the information in this book, you may begin using your laser.

2.3.T This is the end of setup. Turn the key to the OFF position, and then turn the power switch to the OFF position.

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2.4 Changing Procedures on Your Touch Screen

Steps taken to change Procedure Number 18 on the touch-screen display are as follows:

Step 1: Press "**PROCEDURES**" on touch screen.

Step 2: Press "**NEXT**" on touch screen.

Step 3: Press "**PROCEDURES NUMBER 18**" on the touch screen.

Step 4: Press "**EDIT**" on the touch screen.

Step 5: Press "**E**," Press "**SHIFT LOCK**," Press "**n**," "**a**," "**m**," "**e**," "**l**," Press "**SPACE BAR**," Press "**SHIFT LOCK**," Press "**C**," press "**SHIFT LOCK**," Press "**a**," "**r**," "**i**," "**e**," "**s**" on the touch screen.

Step 6: Press "**ENTER**" on the touch screen.

Step 7: Press "**UP / DOWN**" to get 100 µs on touch screen.

Step 8: Press "**UP / DOWN**" to get 300 mJ on touch screen.

Step 9: Press "**UP / DOWN**" to get 10 Hz on touch screen.

Step 10: Press "**SAVE**" on touch screen.

Step 11: Press "**BACK**" on the touch screen, and notice "Procedure Number 18" is now "Caries Removal."

This completes the change.

Procedures of choice may be entered in Procedure Number 19 and Procedure Number 20 by following the steps outlined above.

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2.5 Preset Default Settings

Proc. #	Procedure	µsec	mJ	Hz
1	LANAP Ablation	100	180	20
2	LANAP Hemostasis	550	180	20
3	Abscess Incision	150	160	20
4	Abscess Drainage	150	160	20
5	Aphthous Ulcers	150	160	20
6	Biopsy Incisional	100	40	100
7	Biopsy Excisional	100	40	100
8	ST Crown Lengthen	150	60	50
9	Diode-Like Setting	100	40	100
10	Fibroma Removal	100	40	100
11	Frenectomy	100	40	100
12	Gingivectomy	100	180	20
13	Hemostasis	550	180	20
14	Hygiene Debridement	150	100	20
15	Sulcular Debridement	150	150	20
16	Tissue Recontouring	100	110	50
17	Troughing	250	180	20
18	Enamel Caries	100	300	10
19				
20				

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3. Beam Delivery System

3.1 FiberFlex™ Fiber Installation

3.1.A The FiberFlex™ fibers are supplied nonsterile in sealed protective packages. The input end has an industry-standard SMA 905 connector, with a metal sleeve bonded over the nut to provide an easy grip. A protective cap is supplied on the SMA ferrule, and must be removed before use. (PLEASE KEEP THIS PROTECTIVE CAP TO REPLACE ON THE CONNECTOR END FERRULE WHEN IT IS REMOVED FROM THE LASER OR STORED). Prior to use, the fiber should be sterilized; see Chapter 7.

Caution: Do not touch the ferrule end of the fiber-optic connector after removing the protective cap. The FiberFlex™ fiber input can be damaged or destroyed by contamination such as fingerprints or dirt.
Do not kink, nick, or tightly coil the FiberFlex™ fiber.

3.1.B Install the FiberFlex™ fiber by aligning the connector end with the laser output (fiberport) (see Figure 1 on page 1-8) and sliding into position until fully seated. Tighten the metal sleeve over the SMA nut by turning the sleeve clockwise until it is finger-tight.

Caution: If the FiberFlex™ fiber is not fully tightened or correctly installed, the fiber input surface will not be in the proper position and could be damaged by the laser.

3.2 FiberFlex™ Fiber Handling

3.2.A Anytime the FiberFlex™ fiber is removed from the laser instrument, be sure to protect the connector end of the fiber from contamination and scratches by replacing the protective cap that was supplied on the SMA ferrule. The optical surfaces of the FiberFlex™ fiber are very sensitive to contamination that seriously degrades fiber performance and reduces its life.

3.2.B Visually inspect the input (SMA connector) end of the FiberFlex™ fiber regularly. Discoloration or foreign material on the input (SMA connector) end of the optical fiber is an indication of contamination and

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should be cleaned (removed) with alcohol gauze. Contamination that is left may cause low energy output or may make the FiberFlex™ fiber unusable and could actually damage the focusing lens within the PerioLase® instrument.

3.3 Fiber Cleaving

3.3.A To help ensure delivery of a consistent laser-tissue interaction, it is important that the FiberFlex™ fiber be cleaved properly. A clean, flat cleave is vital for proper transmission of the laser energy through the distal end of the FiberFlex™ fiber. The polyimide buffer around the silica fiber is a protective plastic coating and must be scored using the ceramic cleaver. The procedure for cleaving FiberFlex™ fibers is as follows:

3.3.A.i When the laser is in the **READY** mode, only the red aiming beam will be on. A proper cleave is shown by a well-defined circular red spot with no streaks or "comet tails" emanating from the circle itself. To view this, hold the FiberFlex™ fiber tip perpendicular to a flat, light-colored surface approximately 1" (25 mm) away.

3.3.A.ii Determine the smooth edge of the ceramic cleaver by running it lightly and carefully across your bare skin or fingernail. Use the smooth edge to score the fiber.

3.3.A.iii Hold the FiberFlex™ fiber flat against the edge of your gloved forefinger. With your other hand, hold the ceramic cleaver at an approximately 45º angle to the fiber, approximately one-half inch (12 mm) from the end of the fiber. Draw the edge lightly across the fiber, penetrating the polyimide and scoring the glass fiber. You should see the red aiming beam where the polyimide is now scored. Do not bend the fiber to break it. Rather, pull the end of the fiber until it comes off. A good cleave will show a nice round output of the red aiming beam. Dispose of the cleaved tip in a sharps container. Inspect the cleaved FiberFlex™ fiber as described above using the red beam. An acceptable cleave is indicated by a well-defined circle. If comet tails are evident, re-cleave the FiberFlex™ fiber.

3.3.B As the FiberFlex™ fiber continues to be cleaved, it is necessary to strip a portion of the protective "C-flex" jacket (the white protective rubber-like material surrounding the fiber) from the fiber. Use only the stripping tool supplied with the PerioLase® Periodontal Package™ to expose approximately 3" (76 mm) of bare fiber. Always make sure there is enough

jacket material to pass completely through the collet of the TrueFlex™ handpiece. Otherwise, adjusting the length of the fiber beyond the cannula could cause the fiber to slip in the collet. As you do this, you should also check the integrity of the fiber as described in the following procedure.

3.4 FiberFlex™ Fiber Integrity

3.4.A The FiberFlex™ fiber should bend easily and safely in a 2-inch (50-mm) diameter or 1-inch (25-mm) radius of curvature if there are no scratches or other surface defects on it. However, if the fiber surface (polyimide buffer) is scratched or damaged in any way, it may easily break with only a slight bend. A damaged FiberFlex™ fiber that breaks can heat the cannula and burn soft tissue. The outer surface of the silica glass fiber is a thin coating of a yellowish polymer material called polyimide buffer, which helps to protect the FiberFlex™ fiber from scratches and breakage.

3.4.A.i Strip off 3 inches (76 mm) of the C-flex jacket using the stripping tool provided with the laser, making certain that neither the fiber nor the polyimide buffer is scratched or damaged. The bare fiber should feel smooth to the touch. Occasionally, some of the C-flex material is left behind on the fiber, which you can feel. This will rub off lightly with your fingers, and the fiber should feel perfectly smooth. The FiberFlex™ fiber should bend easily to a 2-inch (50-mm) or less diameter without breaking. (Please DO NOT attempt to perform this procedure with the laser firing.)

3.4.A.ii You can also check for scratches using the red aiming beam when the FiberFlex™ fiber is attached to the laser and in **READY** mode. Scratches or defects will show up as red points of light on the bare fiber.

3.4.A.iii Make sure the stripping tool is in good condition and that you use it properly.

a The blades should appear shiny and new.

b Hold the tool in either hand with the arrow facing up and pointed toward the direction you are going to pull.

c Place the jacket into the "V" of the tool and close it firmly. Strip off enough of the jacket to expose usable fiber (3 inches or 76 mm) but such that the TrueFlex™ handpiece can still grip the jacket at the collet and prevent movement of the fiber within the TrueFlex™ handpiece.

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d With your other hand, grip the fiber jacket between your thumb and forefinger close to the stripping tool. Keep the tool perpendicular to the fiber and remove the jacket from the fiber using a quick and firm motion rather than a slow power pull.

e Discard the stripping tool and replace it if you suspect at any time that it is scratching the FiberFlex™ fiber. It is also possible to strip off small amounts of the jacket with your fingers only. Grasp the jacket between your thumb and forefinger of one hand where you wish to strip it. With your other hand, grasp the jacket placing your thumb and forefinger as tight as you can against your other thumb and forefinger squeezing the jacket. This works best if you rotate one of your hands 90° and interlock the thumbs and forefingers even tighter. Then with a quick motion pull the jacket apart pulling equally hard and tight in both directions as you separate the material.

f Test-bend the FiberFlex™ fiber by bending it with your fingers in different directions at approximately a 1-inch (25-mm) radius. (Again, please DO NOT attempt to perform this procedure with the laser firing.)

3.4.A.iv Occasionally as you strip the FiberFlex™ fiber, you may stretch the remaining fiber jacket so that it becomes thinned out and the Collet of the TrueFlex™ handpiece will not hold it in place when tightened. This can be remedied by placing the Collet onto the FiberFlex™ fiber, grasping the fiber at the working tip end and pushing or bunching up the fiber jacket and tightening the Collet into it.

3.4.A.v The reverse scenario may also occur where you may find a part of the FiberFlex™ fiber that is so large that it does not easily go into the TrueFlex™ handpiece. You can remedy this situation by stretching the fiber jacket slightly so that it will pass into the TrueFlex™ handpiece.

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3.5 FiberFlex™ Fiber/TrueFlex™ Handpiece Installation

Note: The TrueFlex™ handpieces (including cannula) are supplied nonsterile prior to use. They should be sterilized; see Chapter 7.

Carefully insert bare FiberFlex™ fiber in through the back end of the TrueFlex™ handpiece until it protrudes the desired distance through the output end of the cannula. The fiber should go through the cannula smoothly, without resistance or scratching. Ensure that the cannula does not scratch the fiber. Tighten the threaded collet onto the TrueFlex™ handpiece to grip the FiberFlex™ fiber snugly. The TrueFlex™ handpiece tightens against the protective jacket of the fiber to hold the FiberFlex™ fiber in the handpiece.

A few reasons that the cannula can scratch the fiber are:

1. Repeated bending of the cannula. This can result in a bend that produced a sharp inside fold.
2. The distal end of the cannula may have been damaged and have a sharp edge from dropping it or hitting other instruments.
3. Debris may have accumulated inside the cannula. Keep it clean using the brushes provided.

3.5.A TrueFlex™ Handpiece Holder

Two handpiece holders are built into the main handle on the front of the unit, one on the left, and one on the right. Simply insert the end of the TrueFlex™ handpiece into the slot and push the handpiece down until it is securely held.

3.5.B FiberFlex™ Fiber Use

The FiberFlex™ fiber has a onetime use warranty. Sterilization does degrade the efficacy of the fiber. To purchase new FiberFlex™ fibers please call Millennium Dental Technologies at 1 (888) 49-LASER (495-2737). Use of fibers not supplied by Millennium Dental Technologies may nullify the PerioLase® MVP-7™ warranty.

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4. Operation

4.1 Protective Measures

Warning: To avoid possible eye damage, never look directly into laser output or at laser light reflected from specular (reflected) surfaces. The treatment laser has a high-power invisible beam. All personnel should wear laser safety glasses when in the same room as the laser when the high-power invisible beam is operating.

Three pairs of laser protective eyewear are provided with the PerioLase® Periodontal Package™: one for the dentist, one for the assistant, and one for the patient. Additional pairs may be purchased from Millennium or from a laser eyewear vendor. They should have an optical density of 4.0 or greater for the 1064-nanometer wavelength.

For eye protection of nearby personnel, the treatment room should be completely closed off and have a door entry. The door should have a sign warning that a Class 4 laser is in use, and could have an interlock switch connected to the laser's remote interlock. For further details refer to the American National Standard for Safe Use of Lasers in Health Care, document number ANSI Z136.3-2011.

4.1.A Remote Interlock

The remote interlock jack on the rear of the instrument can be used to prevent laser emission if a remote switch, such as a door sensor, is opened. The interlock plug supplied with the instrument is shorted internally. To obtain assistance to connect to a remote interlock switch call Millennium Dental Technologies, Inc.

4.1.B Key Control

The key switch controls operation of the instrument. To begin operation, turn the power switch to the ON position. Insert the key and turn the switch from OFF to ON by turning ¼ turn clockwise. The title screen is displayed during start-up, and then the **MAIN MENU** screen will be displayed with the laser in the **STANDBY** mode.

After laser operation and obtaining a printer output, if desired, turn off the key switch and remove the key. The key can only be removed in the OFF position. Only trained and qualified users should have access to the keys.

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4.1.C Footswitch

Depressing an electrical footswitch controls all laser firing. The footswitch has a guard to prevent accidental depressions.

A wired footswitch is provided with the PerioLase® MVP-7™ as standard equipment.

An optional wireless footswitch is available. Refer to the separate "Infrared Wireless Footswitch Operator's Manual" that is provided with the optional wireless footswitch for instructions for use.

4.1.D Touch-Screen Display

The angle of the touch-screen display may be adjusted by loosening the knob on either side of the display. After properly orienting the display screen, fully tighten the knobs.

The touch-screen surface should be cleaned periodically by using any mild general-purpose cleaner. Computer monitor wipes also work well for cleaning the touch-screen surface.

A protective cover is provided for use when the instrument is not in use. Simply slide the cover over the front of the touch-screen display. To store the cover during laser use, simply slide it onto the back of the touch screen.

4.2 Laser Operation

4.2.A Pulse Width, Energy, and Repetition Rate Select

These three controls are on the top row, respectively, of the **MAIN** screen. To set each of these controls, use the up and down buttons. The pulse width shows the laser pulse width in microseconds (μs). The energy display shows the laser pulse energy in millijoules (mJ). The repetition rate display shows the laser pulse repetition rate in pulses per second or hertz (Hz).

There are seven available pulse widths. They are 100 μsec, 150 μsec, 250 μsec, 350 μsec, 450 μsec, 550 μsec, and 650 μsec. For each pulse width there is an array of allowable pulse energies and repetition rates. These values are shown in the tables in Chapter 10. It is important to examine the tables to see what the allowed values are. If you try to set a value outside of the allowed range, a beep will be heard and the screen value will not change. For example, if you are set for 30 Hz, you will not be able to increase the pulse energy above 200 mJ. In order to further increase the pulse energy, you must first lower the repetition rate to 20 Hz. Note that the maximum average power allowed for any combination of settings is 6.0 Watts.

These settings can be adjusted in both **STANDBY** and **READY** modes.

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The last used settings are stored in memory, and will be displayed at start-up when the laser is turned off then on again.

4.2.B Average Power

The average power will be automatically calculated and displayed in Watts, e.g., **AVG P = 6.0W**. Remember that the average power in Watts is the product of the pulse energy in joules (J) and the pulse repetition rate in hertz (Hz). The display shows pulse energy in millijoules, the average power displays the energy that has been selected times the repetition rate that has been selected divided by 1000. This formula is (*n* J = *x* mJ X *y* Hz). While the laser is firing this display shows the value actually measured by the laser's internal energy monitor.

4.2.C Standby Mode

When first turned on, the PerioLase® enters the **STANDBY** mode. This is indicated by the status display just beneath the average power display. When the PerioLase® is in **STANDBY**, the control panel is active and can be modified and set to the desired parameters. The laser head is not powered, and the footswitch will not cause laser emission. The **STANDBY** mode can be set at any time by pressing the "**STANDBY**" button.

4.2.D Ready Mode

Pressing the "**READY**" button enters the **READY** mode. The status display shows READY, the cooling pump will start, and the aiming beam will turn on in about two seconds. When the footswitch is pressed in this mode, the PerioLase® will provide pulsed laser output at the selected settings until the footswitch is released.

Parameters can be adjusted while in **READY** mode. To do so, release the footswitch, and set the new parameters. Allow 3 to 5 seconds to elapse before pressing the footswitch again. This will allow the laser to reset the parameters appropriately and will prevent a possible E-Code appearance.

4.2.E Laser Emission Indicator

The status display on the touch screen shows the word "**LASER**" flashing when the laser is emitting the surgical beam. In addition, an audible click can be heard with each laser pulse, the loudness of the click will lessen or greaten as the wattage setting is changed. The higher the wattage the greater the click; this is normal.

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4.2.F Joules Counter

The display "**JOULES = 0 J**" just beneath the status display reads the total cumulative number of joules delivered by the PerioLase® since the last reset. This value is reset to zero by touching the clear joules button, designated "**CLR J**," just beneath the total joules display, by touching the print button and completing a printout, or when the laser is turned off.

4.2.G Procedures

The "**PROCEDURES**" button on the **MAIN** screen allows access of up to 20 predetermined setting combinations of pulse width, energy, and repetition rate for specific laser treatments. Pressing the "**PROCEDURES**" button accesses the **PROCEDURE SELECTION MENU** screen.

4.2.G.i Procedure Selection Menu

This menu shows the first 10 procedure choices. Pressing the "**NEXT**" button shows the second 10 procedure choices. Repeatedly pressing "**NEXT**" cycles the two selection screens. "**MAIN**" returns you to the **MAIN** screen.

Pressing any of the procedure buttons takes you to the **PROCEDURE OPERATING** screen for the procedure selected.

4.2.G.ii Procedure Operating Screen

The **PROCEDURE OPERATING** screen allows you to fire the laser with the predetermined pulse width, pulse energy, and repetition rate for that particular procedure. This screen also allows you to adjust the operating parameters as desired. To store the adjusted values for that procedure, press the "**SAVE**" button. To edit the name of the procedure, or enter an entirely different procedure, press the "**EDIT**" button. This takes you to the **PROCEDURE NAME EDIT** screen. To return to the original values of name and operating parameters, press the "**DEFAULT**" button.

4.2.G.iii Procedure Name Edit Screen

Entering the **EDIT** screen replaces the previous name with the name entered on this screen with the alphanumeric pad. If nothing is entered, the name will be blank. Again, pressing the "**DEFAULT**" button on the **PROCEDURE OPERATING** screen will restore the original name and operating parameters.

4.2.H Presets

There are three preset buttons on the **MAIN** screen, labeled "**P1**," "**P2**," and "**P3**." For **each** of the seven pulse width settings, there are three possible combinations of energy and repetition rate that can be stored for one-button

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access. The same pulse width must be used for each of the preset conditions. Preset buttons cannot change the pulse width. To program a preset, after selecting the desired pulse width press the energy and repetition rate select buttons until the desired parameters are displayed. Next, press and hold the desired preset button until an audible beep is heard (approximately two seconds). The next time these parameters are desired, press and release the preset button. Each time the pulse width is changed, a different group of three presets becomes available.

4.2.I Setup

Pressing the "**SETUP**" button accesses the **SETUP MENU** screen. This screen offers three choices: "**PATIENT INFO**," "**USER INFO**," or "**CONTROL PANEL**."

4.2.I.i Patient Info

Pressing this button accesses the first of three screens that allows entry of the Patient's Last Name, Patient's First Name, and Patient Code. This button should be used if you want to enter the patient information on the printout. Use the alphanumeric button pad to enter patient information and then press enter to confirm the entry. Enter the Patient's Last Name, then the Patient's First Name, and then there is a **PATIENT CODE** option screen. This information will remain in the system until you enter this screen again. Entering this screen deletes the previous name. If nothing is entered, the name and code will be blank. This information is printed and used on the printout only for record-keeping purposes.

4.2.I.ii User Info

Pressing this button accesses the **USER INFO SETUP** screen that displays and allows the editing of up to three sets of User Info as User's Last Name, User's First Name, and User Code. Press the respective "**EDIT USER # (1, 2, or 3)**" button to edit any of the three "**USER INFO**" buttons. This button should be used only when you want to enter new user information. Entering this screen replaces the previous name with the name that is entered on this screen. If nothing is entered, the name will be blank and nothing will be printed in this space on the printout. This information is used on the printout only for record-keeping purposes. Once all the information is entered in any or all of the User Information sets, this screen does not need to be entered again until an additional doctor is added or the information changes. From the **MAIN** screen, choose the "**USER # 1, 2, or 3**" button to pick the User # desired on the printout. This is a rotary switch that will continue to move to the next user; one, two, or three and back to one again as you continue to touch the button.

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4.2.I.iii Control Panel

Pressing this button accesses a **SETUP** screen that allows the following adjustments and setups:

TIME and **DATE**: This information is for use on the printout. Use the plus and minus buttons below each item to make changes.

SCREEN CONTRAST: Allows adjustment of the touch screen display for optimum visibility. Use the plus and minus buttons below this item to make changes.

AIMING BEAM INTENSITY: Allows adjustment of the red aiming beam transmitted through the FiberFlex™ fiber. Use the plus and minus buttons below this item to change it. There are five intensity levels available.
5 is full intensity, 4, 3, 2, and 1 are lower intensities, and 0 is off.

4.2.J USER

This button scrolls through the three possible sets of User Info for use on the printout. It works as a rotary switch that will continue to move to the next user; one, two, or three and back to one again as you continue to touch the button. The "**USER #**" displayed is the user name that will be printed.

4.2.K PRINT

This button causes the printer to start a print cycle. The printout consists of the following information:

Date:
Time:
User Number:
User Last Name:
User First Name:
User Code:
Patient Last Name:
Patient First Name:
Patient Code:
Total Joules delivered by the laser at each of the seven different pulse width settings:
Total Cumulative Joules delivered by the laser:

The number of joules delivered is counted from the last joules counter reset, the last printout, or when the key is turned on.

After the printout is completed, press the "**EXIT**" button to return to the **MAIN** screen.

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4.2.L Power Meter

The PerioLase® Laser has a built-in power meter which enables the user to confirm the actual laser power being emitted at the FiberFlex™ fiber tip with the power being displayed on the touch screen. This meter is located on the front of the unit, below the fiber output port, and above the "**LASER STOP**" button and the key switch. To obtain an accurate reading from this meter, the tip of the FiberFlex™ fiber must be clean and properly cleaved. See Chapter 3. The FiberFlex™ fiber should be positioned perpendicular to and ≈3 to 5 mm away from the center of the window in the power meter opening. The power settings should be at or greater than 1 Watt. The laser beam is then delivered into the window. Do not contact the window (or any other part of the laser) with the FiberFlex™ fiber tip, or it will cause damage to the window (or that part of the laser). The **POWER-MEASURING** screen will appear on the touch screen automatically when it detects a power level of 1 Watt or greater. This screen shows the actual value read by the built-in power meter, as well as the power level set by the pulse energy and repetition rate.

To return to the **MAIN** operating screen press "**EXIT**." To change the output energy, return to the **MAIN** operating screen, make the desired change, and begin again.

4.2.M Laser Stop

To immediately terminate laser emission, press the red "**LASER STOP**" button located on the front of the instrument above the key switch. The PerioLase® Laser will automatically go through a restart sequence and return to the **MAIN** operating screen in **STANDBY** mode.

4.3 Printer Operation

4.3.A Paper Change Procedure

The printer is held in place by a push-and-release latch with a magnet. To release, gently push in the printer face bezel or printer front panel and release. The printer unit will slide forward and protrude past the laser front bezel. Grasp the front panel of the printer and pull, sliding the printer forward.

Remove the front panel by pressing the front panel release latch on the left side of the front panel. Then pull out the printer chassis until the paper roll shaft is exposed. At the bottom front of the printer is a lever that releases the roller head pressure. Open this lever by pulling the tip of the lever forward. Remove the old paper roll from the printer. Insert a new roll of paper and feed the paper into the paper track until the edge is about 1 inch (25 mm) past the front of the printer. Close the roller head pressure lever. Push the chassis back into the case. Replace the front panel, being sure to

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insert the paper into the cutter slot paper guide as you do so. Re-attach the front panel by positioning the right side of the front panel first, rotating it like a door until the latch on the left side snaps closed. Push the entire unit back fully until it engages the rear latch magnet. Close the push-and-release latch so that the front panel is flush with the laser front bezel.

PerioLase® units manufactured after January 1, 2014 utilize a different printer setup as described below.

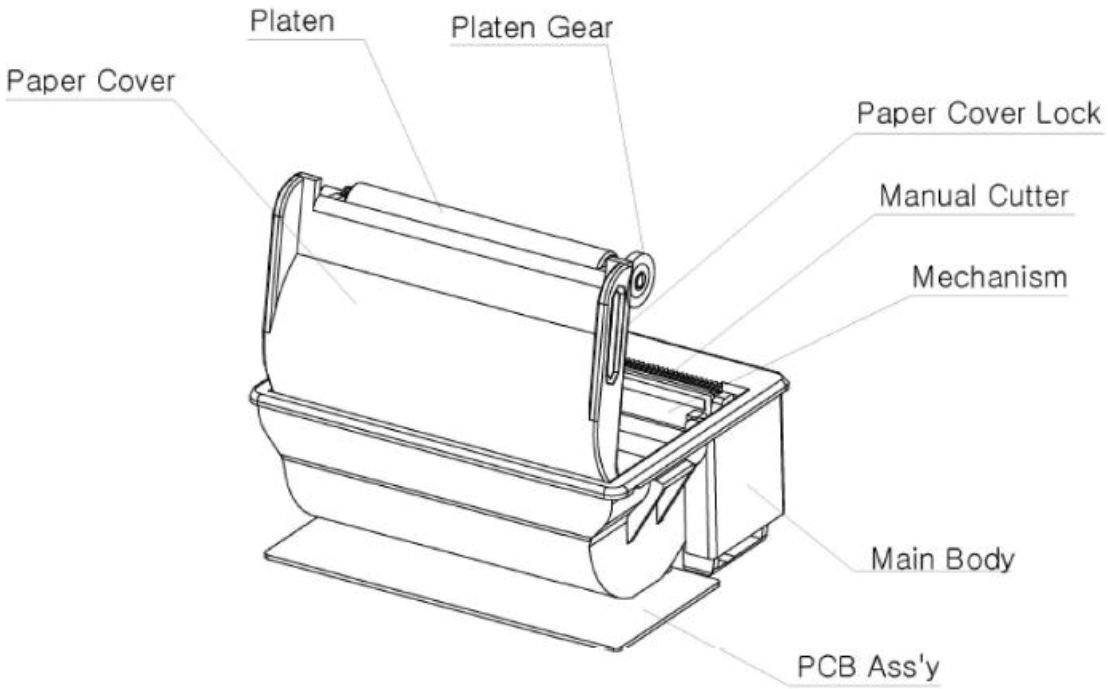

Figure 3: Printer Assembly for PerioLase® Manufactured After January 1, 2014

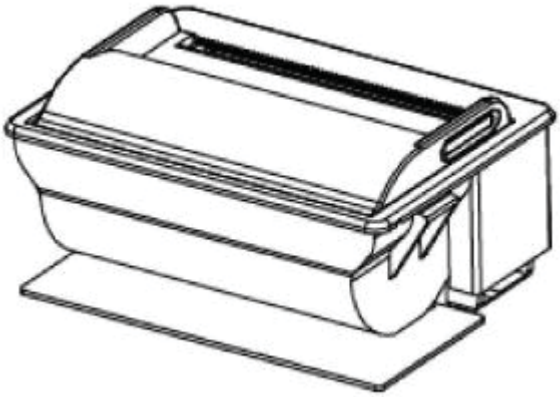

Figure 4: Printer

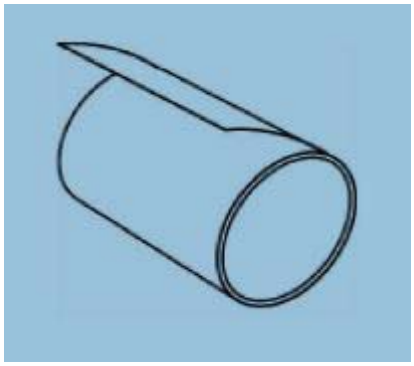

Figure 5: Paper Roll

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NOTE: Do not use paper rolls that have the paper glued to the roll core because the printer cannot detect the paper end correctly.

Be sure to note the proper direction that the paper comes off the roll, as illustrated below.

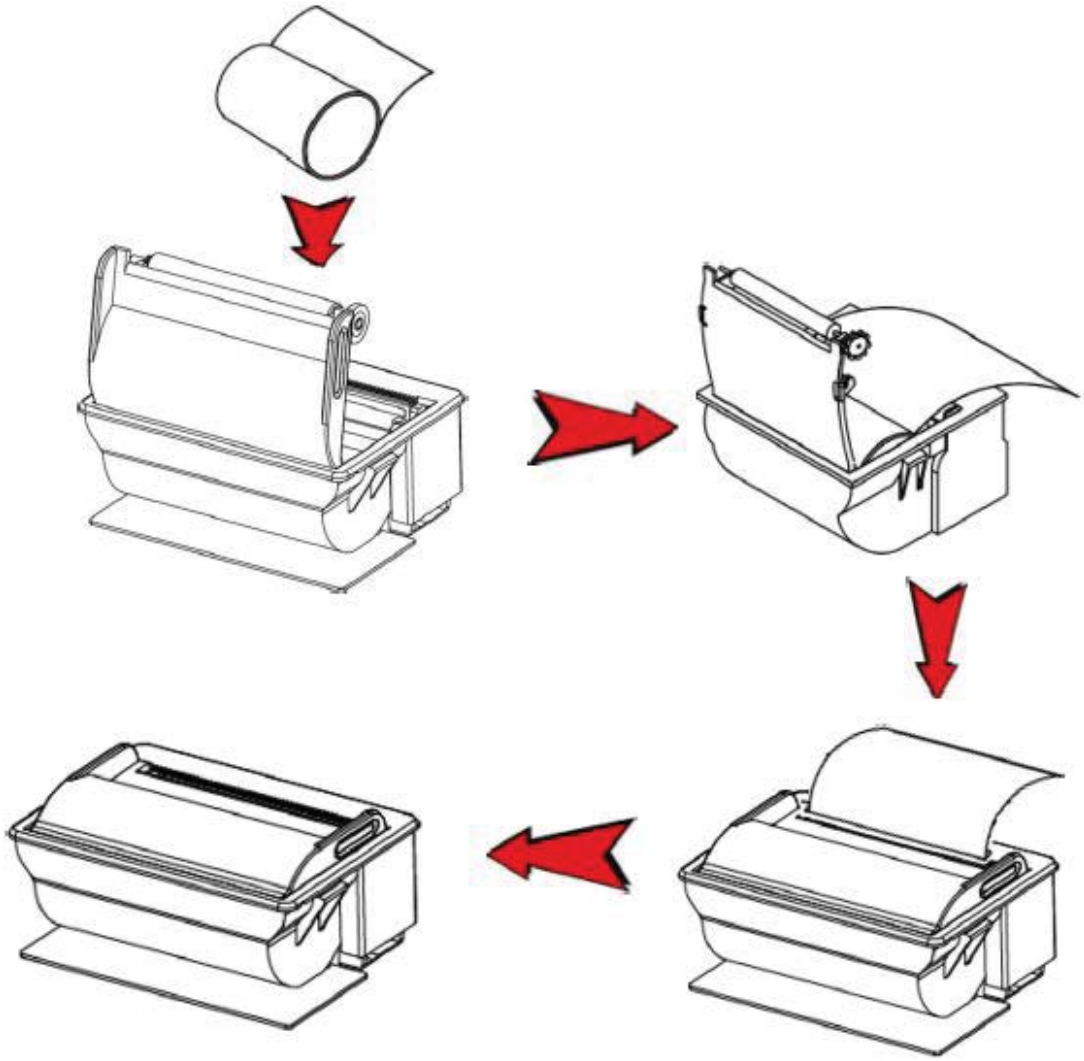

Figure 6: Paper Roll Loading Sequence

Pull out a small amount of paper and then close the printer cover as shown, then tear off the excess paper.

4.3.B Paper Feed

Press the "**PAPER FEED**" button, located in the inset at the lower left of the printer face bezel or printer front panel, one time to feed a small amount of paper. Hold the button down to feed paper continuously.

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4.3.C Printer Repair

If the occasion should ever occur that the printer needs repair it can be removed from the PerioLase® unit and returned for repair separately. Should this need ever occur please call Millennium for assistance and instructions on how to accomplish that at 1 (888) 495-2799.

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5. Indications for Use

The ***PerioLase® Nd:YAG Pulsed Dental Laser System*** is to provide the ability to perform intraoral soft tissue dental, general, oral maxillofacial, and cosmetic surgery. The PerioLase is intended for ablating, incising, excising, vaporization and coagulation of soft tissues using a contact fiber-optic delivery system. The device will be used in the following areas: general and cosmetic dentistry, otolaryngology, arthroscopy, gastroenterology, general surgery, dermatology and plastic surgery, neurosurgery, gynecology, urology, ophthalmology, and pulmonary surgery.

The following are the oropharyngeal indications for use for which the device will be marketed:

- Abscess incision and drainage
- Aphthous ulcers treatment
- Biopsies excision and incision
- Crown lengthening
- Hemostatic assistance
- Fibroma removal
- Frenectomy
- Frenotomy
- Gingival incision and excision
- Gingivectomy
- Gingivoplasty
- Operculectomy
- Oral papillectomy
- Tissue retraction for impression
- Vestibuloplasty
- Selective ablation of enamel (first degree) caries
- Exposure of unerupted / partially erupted teeth
- Implant recovery
- Lesion (tumor) removal
- Leukoplakia
- Pulpotomy
- Pulpotomy as adjunct to root canal therapy

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- Removal of filling material such as gutta-percha or resin as adjunct treatment during root canal retreatment
- Sulcular debridement (removal of diseased or inflamed soft tissue in the periodontal pocket) to improve clinical indices including gingival index, gingival bleeding index, probe depth, attachment level, and tooth mobility
- Laser-assisted new attachment procedure (cementum-mediated periodontal ligament new-attachment to the root surface in the absence of long junctional epithelium)
- Periodontal regeneration – true regeneration of the attachment apparatus (new cementum, new periodontal ligament, and new alveolar bone) on a previously diseased root surface when used specifically in the LANAP® Protocol

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6. Clinical Guidelines

Safety – It is essential that all safety precautions as recommended in the owner's literature be carefully observed, especially with respect to the wearing of protective eyewear by the patient, practitioner, and attending staff. The development of eye-hand-foot coordination while using the laser instrument's handpieces and foot control is important to avoid inadvertent laser operation when the TrueFlex™ handpiece is removed from the target tissue. Measure and compare the extension of the fiber from the TrueFlex™ handpiece before and after performing a laser procedure to ensure no fragment of the fiber has broken off during a procedure. **Repeated breakage of the fiber is an indication that the cannula or contaminants in the TrueFlex™ handpiece are causing abrasion of the polyimide cladding and the cannula should be cleaned or replaced.**

Vaporization of Soft Tissue – Effective vaporization of soft tissue requires use of a properly prepared contact fiber-optic tip. When performing soft tissue procedures, periodically clean the FiberFlex™ fiber tip by wiping the fiber with a wet or dry cotton 2-by-2 to remove any excess buildup. Periodically check the condition of the red aiming beam spot on a surface to verify that an effective cleave of the FiberFlex™ fiber is maintained (refer to Chapter 3 for cleaving instructions).

Metals – Care should be taken while operating at the higher energy levels around nonprecious metals used in amalgams, implant posts, and prostheses. These materials readily conduct the laser's thermal energy. If laser energy comes in contact with such metals, a loud, distinct popping will be recognized, and irradiation of that area should be avoided and stopped immediately. Precious metals are not as interactive to the laser energy but should be avoided whenever possible.

Plume Control – In general, the plume created by the interaction of the FR pulsed Nd:YAG laser and biological tissue or certain dental material is relatively minor when compared with other lasers. Use of a high-volume evacuation system during lasing is recommended to minimize inadvertent dispersal of the plume and odor.

Bone – Avoid excessive or repeated direct exposure on osseous tissue with the laser energy.

Patient Discomfort – Make certain the patient has sufficient anesthesia for the desired procedure. Describe in advance the possibility of sounds and smells and try to avoid them. The high-volume evacuation system should be used a few millimeters from the surgical site while lasing to avoid (as much as possible) the patient experiencing any odors.

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6.1 Clinical Procedures

6.1.A LANAP® Protocol (US Patent #5,642,997)

Anesthetize the area, usually the two quadrants on one side:

a. To make the patient comfortable.

b. To accurately measure to full depth of the diseased pocket.

c. To be aggressive in the extent of mechanical and laser manipulation.

Measure and record pocket depths with a periodontal probe to determine, under anesthesia, the full depth of the diseased pocket.

Using a contact laser FiberFlex™ fiber oriented along the long axis of the tooth, create a gingival trough by denaturing the free gingival margin and the internal epithelial lining of the periodontal pocket thereby aiding in exposing the root surface.

Recommended settings: 3.5 Watts to tissue, 150-μsec duration, 20 Hz.

Long axis orientation defines the direction of the laser FiberFlex™ fiber for the proper initial treatment.

Gingival troughing opens the root surface for visualization.

Denaturing the free gingival margin:

a. Removes accretions and pathogens within the tissue of the free margin.

b. Provides hemostasis for better visualization.

c. Further defines the tissue margins preceding mechanical instrumentation.

d. Preserves the integrity of the mucosa by releasing tissue tension prior to mechanical manipulation.

e. Dissects out the separation between the free gingival margin and the fibrous collagen matrix, thus aiding in the maintenance of the crest of the gingival margin.

Denature the inner pocket epithelium around the entire tooth, to the depth of the probe readings. (Do not attempt to break through the mucogingival junction.)

The "hot-tip" effect provides the selective removal of sulcular and pocket epithelium and granulomatous tissue without removing substantially any granulation and connective fibrous tissue, and does so circumferentially.

As necessary, remove the denatured tissue that accumulates on the tip of the laser FiberFlex™ fiber.

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Ultrasonically scale all root surfaces to the depth of pocket. The intent is to remove all foreign structures and substances from the pocket to allow adhesion of the soft tissue to the clean tooth surface. Do attempt to break through the mucogingival junction with the ultrasonic.

Using the FiberFlex™ fiber (preferably a 360-µm or 400-µm fiber), explore for remaining calculus and/or root roughness. These small fibers are very adept at detection of surface irregularities.

Recommended settings: 3.25 Watts to tissue, 650-µsec duration, 20 Hz.

Lase the pocket to**:** disinfect tissue, create hemostasis, cauterize free nerve endings, and seal lymphatics.

Approximate the wound edges. Compress tissue with wet gauze against the tooth from both a facial and lingual direction in order to permit only a thin clot to form between the tissue and the tooth.

Eliminate all occlusal interferences, centric, working, and balancing. For best results, this step is imperative. It allows the wound to heal and the periodontal ligament to regenerate. The laser modifies the tissue to allow new attachment to take place but if the trauma of malocclusion continues, the tissue cannot withstand this trauma and begins to break down immediately.

Prescribe medications for home use (regimens are outlined in **6.1.B.i** below) and review postoperative care with the patient.

Take alginate impressions for an "Occlusal Guard." This will be delivered at a subsequent postoperative appointment and adjusted as needed for tooth/teeth stabilization.

Postoperative appointment should be at 7 to 10 days. Do a thorough occlusal adjustment at each follow-up visit. This treatment should continue periodically until healing is complete.

Take pocket-depth readings only after 6 months and during continuing care appointments as desired.

6.1.B Medicines Used with LANAP® Protocol

To realize the full potential therapy, maximize healing, and obtain the best long-term prospects for stable periodontal health, it is extremely important that any and all medicines prescribed be taken as directed (unless allergy or side effects occur). Since pain is not a common result of laser therapy, pain medicine is not often prescribed. However, nonsteroidal anti-inflammatory drugs (NSAIDs) are routinely prescribed for their beneficial effects in fighting harmful hormones (prostaglandins) that interfere with optimal periodontal tissue healing. NSAIDs are also commonly used as pain medication, but this is not the primary reason for prescribing these medications for a period of about one week.

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Prescribe any one of the four antibiotic regimens as appropriate for the patient, along with an anti-inflammatory medication and the antibiotic mouthwash described below.

6.1.B.i ANTIBIOTIC MEDICATIONS

a ***Regimen I***

- Amoxicillin or [AMOXIL®] (500 mg)

  Disp: 28 Tabs

  Sig: One tab TID (three times per day) until gone.

b ***Regimen II***

- Metronidazole [FLAGYL®] (250 mg) **AND**
- Amoxicillin or [AUGMENTIN®] (250 mg)

  Disp: 24 Tabs of each

  Sig: One tab of each, TID (two times per day) for 8 days.

Inhibits: *Aggregatibacter actimomycetemcomitans, Peptostreptococcus micros*, and gram-negative rods.

IMPORTANT SIDE EFFECTS OF Metronidazole:

- Must not ingest alcohol of any kind! Metronidazole is an analog of ANTABUSE®, thus alcohol and this medicine will make one very sick!
- Some people experience a "white" coating on the top of their tongue. It is nothing to be concerned about. However, should this occur, discontinue medicine.

c ***Regimen III***

- Metronidazole [FLAGYL®] (250 mg) **AND**
- Ciprofloxacin [CIPRO®] (250 mg)

  Disp: 16 Tabs of each

  Sig: One tab of each, BID (two times per day) for 8 days.

Inhibits: Enteric rods, pseudomonads, and staphylococci, in combination with other anaerobic and facultative pathogens.

d ***Regimen IV***

- Clindamycin [CLEOCIN®] (300 mg) **AND**
- Ciprofloxacin [CIPRO®] (250 mg)

Disp: 16 Tabs of each

Sig: One tab of each, BID (two times per day) for 8 days.

Inhibits: *Peptostreptococcus micros* infections in patients hypersensitive to penicillin.

6.1.B.ii NONSTEROIDAL ANTI-INFLAMMATORY DRUGS (NSAIDs)

TAKEN *IN ADDITION* TO THE ANTIBIOTIC REGIMENS I, II, III, **or** IV.

a Ibuprofen (MOTRIN®)

800 mg tablets

Disp: 23 tabs

Sig: 1 tab BID (two times per day) for 3 days then p.r.n. for pain.

OR

b Naproxin Sodium (ANAPROX®)

275 mg tablets (blue)

Disp: 23 tabs

Sig: 2 tabs stat & 1 tab BID (two times per day) for 3 days then p.r.n. for pain

6.1.B.iii ANTIBIOTIC MOUTHWASH

TAKEN *IN ADDITION* TO THE MEDICATIONS DESCRIBED ABOVE.

Used as directed for one week following each treatment

a Peridex™ or PerioGard® 16 oz. Bottle

Disp: 2 bottles

Sig: Use as directed.

7. Sterilization

PerioLase® MVP-7™ – The beam delivery system may be sterilized using either steam or ethylene oxide.

7.1 Preparing the Beam Delivery System

7.1.A Loosen the adjustable collet on the TrueFlex™ handpiece (see figure below) and remove the FiberFlex™ fiber completely from the TrueFlex™ handpiece by sliding it out.

Figure 7: TrueFlex™ Handpiece

7.1.B Use the provided cleaving tool to cleave the tip of the FiberFlex™ fiber as described in section 3.3 of the Operator's Manual.

7.1.C Use the provided stripping tool to remove enough of the C-flex jacket material to expose approximately 3" (76 mm) of bare fiber. Areas where blood has been wicked up between the C-Flex jacket and the fiber must be cut off prior to sterilization. Always make sure there is enough jacket material to pass completely through the collet of the TrueFlex™ handpiece. Otherwise, adjusting the length of the fiber beyond the cannula could cause the FiberFlex™ fiber to slip in the collet.

7.1.D Unscrew and separate the TrueFlex™ handpiece body, collet, and stainless steel cannula.

7.1.D.i Ultrasonic Cleaning Procedure

Rinse all parts under warm tap water. Using warm, clean, soapy tap water on the cannula, brush the inside of the cannula with the provided cannula brush. For best results place the handle end of the cannula brush into the cannula first and pull the brush end through the cannula rather than trying to push the brush headfirst through the cannula. It may be helpful to bend the cannula to less than 60° to clean it. Also, use the cannula brush to clean the inside of the TrueFlex™ handpiece body with warm soapy water. Rinse thoroughly then place parts inside a ziplock

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bag with some clean soapy water. Seal the bag and run through a cycle in an ultrasonic cleaner. Rinse thoroughly and prepare for sterilization.

7.1.D.ii Alternative Cleaning Procedure

Rinse all parts under warm tap water. Using warm, clean, soapy tap water on the cannula, brush the inside of the cannula with the provided cannula brush. For best results place the handle end of the cannula brush into the cannula first and pull the brush end through the cannula rather than trying to push the brush headfirst through the cannula. It may be helpful to bend the cannula to less than 60° to clean it. Also, use the cannula brush to clean the inside of the TrueFlex™ handpiece body with warm soapy water. Rinse thoroughly and prepare for sterilization.

7.1.E Use a soft brush or cloth to clean the cleaving tool with warm, clean, soapy water. Rinse and prepare for sterilization. Do not place the cleaving tool in an ultrasonic bath.

7.1.F The fiber stripping tool is to be cleaned / sterilized according to the manufacturer's instructions.

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7.2 Steam Sterilization Procedure

The steam sterilization procedure should be performed in accordance with the directions of the manufacturer of the autoclave.

7.2.A Coil the FiberFlex™ fiber (not less than 6-inch (15.2-cm) coil diameter) and place the fiber into an autoclave pouch for sterilization. Use a pouch at least 8" by 12" (20.3 by 30.4 cm). **Note:** Do not place the rubber cap that came on the FiberFlex™ Fiber back on the fiber prior to sterilization.

7.2.B Place the TrueFlex™ handpiece parts and cleaving tool into a small autoclave pouch or pouches.

7.2.C Sterilize by steam autoclave for 10 minutes at a minimum of 132°C (270°F). Allow to cool before handling.

7.3 Ethylene Oxide Sterilization Procedure

EtO gas sterilization should be performed in accordance with the directions of the manufacturer of the sterilizer.

7.3.A Conditioning cycle: Relative humidity 55 – 75%. EtO 650 mg/l concentration, 100% EtO.

7.3.B Exposure cycle: 55°C (130°F), 3 hours and 30 minutes. Gassing 14.1 ± 0.5" Hg (358 ± 12.7 mm Hg).

7.3.C Aeration cycle: 43 – 55°C (maximum 130°F), 12 hours minimum.

Note: The optical surfaces of the beam delivery FiberFlex™ fiber are very sensitive to contamination. The autoclave itself must be clean. If the same autoclave is used for sterilizing high- or low-speed air-turbine handpieces, the lubricating oils can contaminate the autoclave and be transferred to the optical surfaces of the FiberFlex™ fibers. This will seriously degrade the performance of the FiberFlex™ fibers and reduce their life. Clean the autoclave on a regular basis. **It is strongly recommended to clean the autoclave on a once-per-week schedule,** the normal cleaning schedule recommended by most major autoclave manufacturers. If any of the interior surfaces of the autoclave feel oily to the touch, it should be cleaned before sterilizing any optical FiberFlex™ fibers. Follow the manufacturer's instructions for cleaning.

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8. Maintenance

8.1 Routine Maintenance

Routine maintenance services are to be performed on an annual basis to maintain the unit at full operating potential. To schedule a routine maintenance please contact Millennium Dental Technologies directly at 1 (888) 495-2799.

8.2 Cleaning

The laser touch screen can be cleaned with mild cleansers and water. Use a wiper moistened with the cleaner. Avoid spraying or pouring liquids directly onto the instrument or into any openings.

8.3 Calibration

When the internal power meter does not measure the same output energy as is called for on the touch screen these procedures should be followed:

8.3.A Calibration Procedure

8.3.A.i Connect a new 360-µm FiberFlex™ fiber with a clean, cleaved output end to the instrument. Set the laser parameters to 100 µsec, 100 mJ, and 50 Hz and press the "**READY**" button.

8.3.A.ii Direct the fiber output onto a calibrated power meter detector. Fire the laser with the footswitch and note the stable power reading on the power meter after 3 to 5 seconds. If the power meter reads 4.7 to 5.3 Watts, the instrument is calibrated. Return the original FiberFlex™ fiber to the laser. If the problem output persists, discard the FiberFlex™ fiber.

8.3.A.iii If the power meter reads less than 4.7 Watts, check first for dirt or damage on the fiber input, or a poor cleave on the output. Try a second fiber, if available.

8.3.A.iv If the calibration is still off, call Millennium Dental Technologies for assistance at 1 (888) 495-2799.

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9. Troubleshooting

9.1 Check Codes

The control system will beep and display check codes on the control panel if it detects a correctable condition. The check codes are displayed on the **MAIN** screen as well as the **PROCEDURE OPERATING** screen just above the "**STANDBY**" button.

The four check codes are:

FIB or FIBER: Fiber sensor. The controller did not detect a beam delivery fiber installed. Check that the FiberFlex™ fiber is installed and that the SMA connector is fully seated and finger-tight.

INT or INTERLOCK: Remote interlock. The remote interlock connector is open. Check that the shorting plug is installed or that the remote switch is closed.

TEMP or TEMPERATURE: Temperature limit. If the laser coolant temperature reaches the maximum allowed, the controller will beep once and enter the **STANDBY** mode. Once the coolant temperature drops below the maximum level, the check code will turn off and the operator may continue to use the laser.

FSW or FOOTSWITCH: Footswitch not installed. This condition also appears if the footswitch is depressed while in the **STANDBY** mode.

Check that the footswitch is installed and that the connector is fastened on correctly.

For the optional wireless footswitch, check that the toggle switch located beneath the wireless receiver on the back of the laser is toggled to the "Wireless" position.

When the wired footswitch is attached and the toggle switch on the back of the laser is in the "Wired" position, the laser will enter the READY mode and will fire when the wired footswitch is depressed. Use of the wireless footswitch will have no effect on the laser.

When the wired footswitch is not attached and the toggle switch on the back of the laser is in the "Wired" position, the **FSW** or **FOOTSWITCH** check code is displayed. Use of the wireless footswitch will have no effect on the laser.

When the wired footswitch is attached and the toggle switch on the back of the laser is in the "Wireless" position, the laser will enter the **READY** mode but will not fire when the wired footswitch is depressed. No check code is displayed.

When the wired footswitch is attached and the toggle switch on the back of the laser in the "Wired" position, the laser will enter the

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READY mode will not fire when the wireless footswitch is depressed. No check code is displayed.

NOTE: The abbreviated name is displayed if the condition occurs while the system is in **STANDBY** mode, and the full name is displayed if the condition occurs while the system is in **READY** mode. This is for troubleshooting purposes. If these conditions cannot be corrected, please call Millennium Dental Technologies at 1 (888) 495-2799 for assistance.

9.2 Error Codes

If an error code beginning with E followed by a two-digit number, such as E89, is displayed, the user should note the code and call a qualified service representative at 1-888-495-2799. Error codes are listed in the following table.

NOTE: When a fault occurs while in the **READY** mode, and the cause of the fault is corrected, the error code can be cleared by pressing the "**STANDBY**" button.

ERROR CODE	MEANING
E81	Fiber sensor is stuck in the ON state
E82	Temperature sensor indicates < 2°C
E83	Temperature sensor indicates > 80°C
E84	Coolant flow switch is closed when the pump should be off
E85	Coolant flow switch is open when the pump should be on
E88	Insufficient energy detected during firing
E89	Excessive energy detected during firing
E90	High voltage present when it should not be
E93	Energy detector calibration factor corrupted

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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9.3 Fuse Replacement

In the event that the fuse needs replacement, use a standard 1/4" (6.35 mm) diameter Glass-Tube Fuse 3AG, Fast-Acting, 250 VAC, 8 Amp Rating (10 Amp Rating is acceptable) as follows:

Unplug the line cord from the AC inlet at the rear of the instrument.

Use a small, flat-blade screwdriver to open the fuse access panel just above the AC inlet. Use the screwdriver to pull out the red fuse carrier. Remove the old fuse, insert the new fuse, and re-install the fuse carrier. Close the access panel and plug the power cord back in.

CAUTION: If the fuse blows repeatedly, call a qualified service representative at Millennium Dental Technologies at 1-888-495-2799.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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10. Specifications

10.1 Laser Specifications

Working Beam

Wavelength	1.064 microns (1064 nm)
Pulse Energy	20 to 300 mJ
Pulse Width	100 µsec to 650 µsec
Repetition Rate	10 to 100 Hz
Average Power	6 Watts maximum
Laser Classification	Class IV

Aiming Beam

Wavelength	630 to 680 nm
Power	≤ 5.0 milliwatts

Electrical

AC Power	100 - 240 V~, 50/60 Hz, 8A/4A
Fuse	1/4" Diameter Glass-Tube Fuse 3AG, Fast-Acting, 250 VAC, 8 Amp Rating
Duty Cycle	50%, max 10 minutes at 6 W output

Environmental

Temperature	50 to 104 °F (10 to 40 °C)
Relative Humidity	0 to 75 %
Atmospheric Pressure	700 to 1060 hPa (20.6 to 31.3" Hg)

Mechanical

Size	11" X 19" X 25" (27.9 x 48.2 x 63.5 cm)
Weight	45 lbs (20.4 kg)

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10.2 Laser Pulse Parameters

(mJ equals energy per pulse, pps equals pulses per second, and Hz equals Hertz)

100 µsec Pulse width	10 pps or Hz	15 pps or Hz	20 pps or Hz	30 pps or Hz	40 pps or Hz	50 pps or Hz	60 pps or Hz	70 pps or Hz	80 pps or Hz	90 pps or Hz	100 pps or Hz
20 mJ	0.2	0.3	0.4	0.6	0.8	1.0	1.2	1.4	1.6	1.8	2.0
30 mJ	0.3	0.45	0.6	0.9	1.2	1.5	1.8	2.1	2.4	2.7	3.0
40 mJ	0.4	0.6	0.8	1.2	1.6	2.0	2.4	2.8	3.2	3.6	4.0
60 mJ	0.6	0.9	1.2	1.8	2.4	3.0	3.6	4.2	4.8		
80 mJ	0.8	1.2	1.6	2.4	3.2	4.0	4.8				
100 mJ	1.0	1.5	2.0	3.0	4.0	5.0					
110 mJ	1.1	1.65	2.2	3.3	4.4	5.5					
120 mJ	1.2	1.8	2.4	3.6	4.8						
130 mJ	1.3	1.95	2.6	3.9	5.2						
140 mJ	1.4	2.1	2.8	4.2	5.6						
150 mJ	1.5	2.25	3.0	4.5	6.0						
160 mJ	1.6	2.4	3.2	4.8							
170 mJ	1.7	2.55	3.4	5.1							
180 mJ	1.8	2.7	3.6	5.4							
190 mJ	1.9	2.85	3.8	5.7							
200 mJ	2.0	3.0	4.0	6.0							
210 mJ	2.1	3.15	4.2								
220 mJ	2.2	3.3	4.4								
230 mJ	2.3	3.45	4.6								
240 mJ	2.4	3.6	4.8								
250 mJ	2.5	3.75	5.0								
260 mJ	2.6	3.9	5.2								
270 mJ	2.7	4.05	5.4								
280 mJ	2.8	4.2	5.6								
290 mJ	2.9	4.35	5.8								
300 mJ	3.0	4.5	6.0								

Table is in Watts that is average power

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Laser Pulse Parameters (cont.)

(mJ equals energy per pulse, pps equals pulses per second, and Hz equals Hertz)

150 µsec pulse width	10 pps or Hz	15 pps or Hz	20 pps or Hz	30 pps or Hz	40 pps or Hz	50 pps or Hz	60 pps or Hz	70 pps or Hz	80 pps or Hz	90 pps or Hz	100 pps or Hz
20 mJ	0.2	0.3	0.4	0.6	0.8	1.0	1.2	1.4	1.6	1.8	2.0
30 mJ	0.3	0.45	0.6	0.9	1.2	1.5	1.8	2.1	2.4	2.7	3.0
40 mJ	0.4	0.6	0.8	1.2	1.6	2.0	2.4	2.8	3.2	3.6	4.0
60 mJ	0.6	0.9	1.2	1.8	2.4	3.0	3.6	4.2	4.8		
80 mJ	0.8	1.2	1.6	2.4	3.2	4.0	4.8				
100 mJ	1.0	1.5	2.0	3.0	4.0	5.0					
110 mJ	1.1	1.65	2.2	3.3	4.4	5.5					
120 mJ	1.2	1.8	2.4	3.6	4.8						
130 mJ	1.3	1.95	2.6	3.9	5.2						
140 mJ	1.4	2.1	2.8	4.2	5.6						
150 mJ	1.5	2.25	3.0	4.5	6.0						
160 mJ	1.6	2.4	3.2	4.8							
170 mJ	1.7	2.55	3.4	5.1							
180 mJ	1.8	2.7	3.6	5.4							
190 mJ	1.9	2.85	3.8	5.7							
200 mJ	2.0	3.0	4.0	6.0							
210 mJ	2.1	3.15	4.2								
220 mJ	2.2	3.3	4.4								
230 mJ	2.3	3.45	4.6								
240 mJ	2.4	3.6	4.8								
250 mJ	2.5	3.75	5.0								
260 mJ	2.6	3.9	5.2								
270 mJ	2.7	4.05	5.4								
280 mJ	2.8	4.2	5.6								
290 mJ	2.9	4.35	5.8								
300 mJ	3.0	4.5	6.0								

Table is in Watts that is average power

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Laser Pulse Parameters (cont.)

(mJ equals energy per pulse, pps equals pulses per second, and Hz equals Hertz)

250 µsec pulse width	10 pps or Hz	15 pps or Hz	20 pps or Hz	30 pps or Hz	40 pps or Hz	50 pps or Hz	60 pps or Hz	70 pps or Hz	80 pps or Hz	90 pps or Hz	100 pps or Hz
20 mJ											
30 mJ											
40 mJ											
60 mJ	0.6	0.9	1.2	1.8	2.4	3.0	3.6	4.2	4.8		
80 mJ	0.8	1.2	1.6	2.4	3.2	4.0	4.8				
100 mJ	1.0	1.5	2.0	3.0	4.0	5.0					
110 mJ	1.1	1.65	2.2	3.3	4.4	5.5					
120 mJ	1.2	1.8	2.4	3.6	4.8						
130 mJ	1.3	1.95	2.6	3.9	5.2						
140 mJ	1.4	2.1	2.8	4.2	5.6						
150 mJ	1.5	2.25	3.0	4.5	6.0						
160 mJ	1.6	2.4	3.2	4.8							
170 mJ	1.7	2.55	3.4	5.1							
180 mJ	1.8	2.7	3.6	5.4							
190 mJ	1.9	2.85	3.8	5.7							
200 mJ	2.0	3.0	4.0	6.0							
210 mJ	2.1	3.15	4.2								
220 mJ	2.2	3.3	4.4								
230 mJ	2.3	3.45	4.6								
240 mJ	2.4	3.6	4.8								
250 mJ	2.5	3.75	5.0								
260 mJ	2.6	3.9	5.2								
270 mJ	2.7	4.05	5.4								
280 mJ	2.8	4.2	5.6								
290 mJ	2.9	4.35	5.8								
300 mJ	3.0	4.5	6.0								

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Laser Pulse Parameters (cont.)

(mJ equals energy per pulse, pps equals pulses per second, and Hz equals Hertz)

350 µsec pulse width	10 pps or Hz	15 pps or Hz	20 pps or Hz	30 pps or Hz	40 pps or Hz	50 pps or Hz	60 pps or Hz	70 pps or Hz	80 pps or Hz	90 pps or Hz	100 pps or Hz
20 mJ											
30 mJ											
40 mJ											
60 mJ											
80 mJ	0.8	1.2	1.6	2.4	3.2	4.0	4.8				
100 mJ	1.0	1.5	2.0	3.0	4.0	5.0					
110 mJ	1.1	1.65	2.2	3.3	4.4	5.5					
120 mJ	1.2	1.8	2.4	3.6	4.8						
130 mJ	1.3	1.95	2.6	3.9	5.2						
140 mJ	1.4	2.1	2.8	4.2	5.6						
150 mJ	1.5	2.25	3.0	4.5	6.0						
160 mJ	1.6	2.4	3.2	4.8							
170 mJ	1.7	2.55	3.4	5.1							
180 mJ	1.8	2.7	3.6	5.4							
190 mJ	1.9	2.85	3.8	5.7							
200 mJ	2.0	3.0	4.0	6.0							
210 mJ	2.1	3.15	4.2								
220 mJ	2.2	3.3	4.4								
230 mJ	2.3	3.45	4.6								
240 mJ	2.4	3.6	4.8								
250 mJ	2.5	3.75	5.0								
260 mJ	2.6	3.9	5.2								
270 mJ	2.7	4.05	5.4								
280 mJ	2.8	4.2	5.6								
290 mJ	2.9	4.35	5.8								
300 mJ	3.0	4.5	6.0								

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Laser Pulse Parameters (cont.)

(mJ equals energy per pulse, pps equals pulses per second, and Hz equals Hertz)

450 µsec pulse width	10 pps or Hz	15 pps or Hz	20 pps or Hz	30 pps or Hz	40 pps or Hz	50 pps or Hz	60 pps or Hz	70 pps or Hz	80 pps or Hz	90 pps or Hz	100 pps or Hz
20 mJ											
30 mJ											
40 mJ											
60 mJ											
80 mJ											
100 mJ	1.0	1.5	2.0	3.0							
110 mJ	1.1	1.65	2.2	3.3							
120 mJ	1.2	1.8	2.4	3.6							
130 mJ	1.3	1.95	2.6	3.9							
140 mJ	1.4	2.1	2.8	4.2							
150 mJ	1.5	2.25	3.0	4.5							
160 mJ	1.6	2.4	3.2	4.8							
170 mJ	1.7	2.55	3.4	5.1							
180 mJ	1.8	2.7	3.6	5.4							
190 mJ	1.9	2.85	3.8	5.7							
200 mJ	2.0	3.0	4.0	6.0							
210 mJ	2.1	3.15	4.2								
220 mJ	2.2	3.3	4.4								
230 mJ	2.3	3.45	4.6								
240 mJ	2.4	3.6	4.8								
250 mJ	2.5	3.75	5.0								
260 mJ	2.6	3.9	5.2								
270 mJ	2.7	4.05	5.4								
280 mJ	2.8	4.2	5.6								
290 mJ	2.9	4.35	5.8								
300 mJ	3.0	4.5	6.0								

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Laser Pulse Parameters (cont.)

(mJ equals energy per pulse, pps equals pulses per second, and Hz equals Hertz)

550 µsec pulse width	10 pps or Hz	15 pps or Hz	20 pps or Hz	30 pps or Hz	40 pps or Hz	50 pps or Hz	60 pps or Hz	70 pps or Hz	80 pps or Hz	90 pps or Hz	100 pps or Hz
20 mJ											
30 mJ											
40 mJ											
60 mJ											
80 mJ											
100 mJ	1.0	1.5	2.0	3.0							
110 mJ	1.1	1.65	2.2	3.3							
120 mJ	1.2	1.8	2.4	3.6							
130 mJ	1.3	1.95	2.6	3.9							
140 mJ	1.4	2.1	2.8	4.2							
150 mJ	1.5	2.25	3.0	4.5							
160 mJ	1.6	2.4	3.2	4.8							
170 mJ	1.7	2.55	3.4	5.1							
180 mJ	1.8	2.7	3.6	5.4							
190 mJ	1.9	2.85	3.8	5.7							
200 mJ	2.0	3.0	4.0	6.0							
210 mJ	2.1	3.15	4.2								
220 mJ	2.2	3.3	4.4								
230 mJ	2.3	3.45	4.6								
240 mJ	2.4	3.6	4.8								
250 mJ	2.5	3.75	5.0								
260 mJ	2.6	3.9	5.2								
270 mJ	2.7	4.05	5.4								
280 mJ	2.8	4.2	5.6								
290 mJ	2.9	4.35	5.8								
300 mJ	3.0	4.5	6.0								

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Laser Pulse Parameters (cont.)

(mJ equals energy per pulse, pps equals pulses per second, and Hz equals Hertz)

650 µsec pulse width	10 pps or Hz	15 pps or Hz	20 pps or Hz	30 pps or Hz	40 pps or Hz	50 pps or Hz	60 pps or Hz	70 pps or Hz	80 pps or Hz	90 pps or Hz	100 pps or Hz
20 mJ											
30 mJ											
40 mJ											
60 mJ											
80 mJ											
100 mJ											
110 mJ											
120 mJ	1.2	1.8	2.4	3.6							
130 mJ	1.3	1.95	2.6	3.9							
140 mJ	1.4	2.1	2.8	4.2							
150 mJ	1.5	2.25	3.0	4.5							
160 mJ	1.6	2.4	3.2	4.8							
170 mJ	1.7	2.55	3.4	5.1							
180 mJ	1.8	2.7	3.6	5.4							
190 mJ	1.9	2.85	3.8	5.7							
200 mJ	2.0	3.0	4.0	6.0							
210 mJ	2.1	3.15	4.2								
220 mJ	2.2	3.3	4.4								
230 mJ	2.3	3.45	4.6								
240 mJ	2.4	3.6	4.8								
250 mJ	2.5	3.75	5.0								
260 mJ	2.6	3.9	5.2								
270 mJ	2.7	4.05	5.4								
280 mJ	2.8	4.2	5.6								
290 mJ	2.9	4.35	5.8								
300 mJ	3.0	4.5	6.0								

Table is in Watts that is average power

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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10.3 Applicable Standards and Regulations

Designed to meet the following standards and regulations:

IEC 60601-1:1988 + A1:1991 + A2:1995. Medical Electrical Equipment – Part 1: General Requirements for Safety

IEC 60601-1-1 Edition 2.0 (2000). Medical Electrical Equipment – Part 1-1: General Requirements for Safety – Collateral Standard: Safety Requirements for Medical Electrical Systems

IEC 60601-1-2 Edition 3.0 (2007). Medical Electrical Equipment – Part 1-2: General Requirements for Basic Safety and Essential Performance – Collateral Standard: Electromagnetic Compatibility – Requirements and Tests

IEC 60601-1-4 Edition 1.1 Consolidated with Amendment 1 (2000-04). Medical Electrical Equipment – Part 1-4: General Requirements for Safety – Collateral Standard: Programmable Electrical Medical Systems

IEC 60601-2-22 Edition 2.0 (1995). Medical Electrical Equipment – Part 2: Particular Requirements for the Safety of Diagnostic and Therapeutic Laser Equipment

IEC 60825-1 Edition 1.0 (1993). Safety of Laser Products – Part 1: Equipment Classification, Requirements and User's Guide

21 CFR 1040 Performance Standards for Light-Emitting Products. Section 1040.10 Laser Products
Section 1040.11 Specific Purpose Laser Products

Complies with 21 CFR 1040.10 and 1040.11 except for deviations pursuant to Laser Notice No. 50, dated June 24, 2007.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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11. Electromagnetic Compatibility

CAUTION: The PerioLase® MVP-7™ needs special precautions regarding electromagnetic compatibility (EMC) and needs to be installed and put into service according to the EMC information provided in this manual.

Portable and mobile Radio Frequency (RF) communications equipment can affect the PerioLase® MVP-7™.

WARNING: The use of accessories and cables other than those specified by Millennium Dental Technologies, Inc. may result in increased emissions or decreased immunity of the PerioLase® MVP-7™.

Guidance and manufacturer's declaration – electromagnetic emissions		
The PerioLase® MVP-7™ is intended for use in the electromagnetic environment specified below. The customer or the user of the PerioLase® MVP-7™ should assure it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1 Class A	The PerioLase® MVP-7™ uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
Harmonic emissions IEC 61000-3-2	Class A	The PerioLase® MVP-7™ is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Voltage fluctuations / flicker emissions IEC 61000-3-3	Complies	

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Guidance and manufacturer's declaration – electromagnetic immunity			
The PerioLase® MVP-7™ is intended for use in the electromagnetic environment specified below. The customer or the user of the PerioLase® MVP-7™ should assure that it is used in such an environment.			
Immunity test	**IEC 60601 Test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/ output lines	± 2 kV for power supply lines ± 1 kV for input/ output lines	Mains power quality should be that of a typical commercial or hospital environment If the user of the PerioLase® MVP-7™ requires continued operation during power mains interruptions, it is recommended that the PerioLase® MVP-7™ be powered from an uninterruptible power supply.
Surge IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	± 1 kV differential mode ± 2 kV common mode	
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec.	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec.	
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: U_T is the AC mains power voltage prior to application of the test level.			

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Guidance and manufacturer's declaration – electromagnetic immunity			
The PerioLase® MVP-7™ is intended for use in the electromagnetic environment specified below. The customer or the user of the PerioLase® MVP-7™ should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	3 Vrms 3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the PerioLase® MVP-7™, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol:
NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.			
[a]Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast, cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the PerioLase® MVP-7™ is used exceeds the applicable RF compliance level above, the PerioLase® MVP-7™ should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the PerioLase® MVP-7™. [b]Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Recommended separation distances between portable and mobile RF communications equipment and the PerioLase® MVP-7™

The PerioLase® MVP-7™ is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the PerioLase® MVP-7™ can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the PerioLase® MVP-7™ as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Test Report (Appendix C2) EN 60601-1-2:2001, A1:2006 IEC 60601-1-2:2001, A1:2004 Report Reference No. (b)(4) PerioLase MVP-7 Millennium Dental Technologies Date: 9/30/09	
Test Description	**Verdict**
IEC 60601-1-2	
IEC 61000-4-2 Electrostatic Discharge	Pass
IEC 61000-4-3 RF Electromagnetic Field	Pass
IEC 61000-4-4 Electrical Fast Transient/Burst	Pass
IEC 61000-4-5 Surge	Pass
IEC 61000-4-6 Conducted RF Immunity	Pass
IEC 61000-4-8 Power Frequency Magnetic Field	Pass
IEC 61000-4-11 Voltage Dips, Short Interruption	Pass
IEC 61000-3-2 Harmonics	Pass
IEC 61000-3-3 Flicker	Pass
CISPR 11 Radiated Emissions	Pass
CISPR 11 Conducted Emissions	Pass
EN 60601-1-2 Section 6	
6.8.2.201 Instructions for Use	Complies
6.8.3.201 Technical Description	Complies
No additions, deviations from the standard were applied.	

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Test Report IEC 60601-1 / EN 60601 – 1 (Appendix C3)
Medical electrical equipment
Part 1: General requirements for safety
Report Reference N (b)(4)
PerioLase MVP-7
Millennium Dental Technologies
Date: 10/30/09

IEC 60601:1988 + A1:1991 + A2:1995

Clause	Requirement + Test	Verdict
3	General Requirements	Pass
5	Classification	Pass
6	Identification, Marking and Documents	Pass
7	Power Input	Pass
10	Environmental Conditions	Pass
14	Requirements Related to Classification	Pass
15	Limitation of Voltage and/or Energy	Pass
16	Enclosures and Protective Covers	Pass
17	Separation	Pass
18	Protective Earthing, Functional Earthing and Potential Equalization	Pass
19	Continuous Leakage Currents and Patient Auxiliary Currents	Pass
20	Dielectric Strength	Pass
21	Mechanical Strength	Pass
23	Surfaces, Corners and Edges	Pass
24	Stability in Normal Use	Pass
36	Electromagnetic Compatibility	Pass
42	Excessive Temperatures	Pass
43	Fire Prevention	Pass
44	Overflow, Spillage, Leakage, Humidity, Ingress of Liquids, Cleaning, Sterilization and Disinfection	Pass
49	Interruption of Power Supply	Pass
51	Protection Against Hazardous Output	Pass
52	Abnormal Operation and Fault Conditions	Pass
56	Components and General Assembly	Pass
57	Mains Parts, Components and Layout	Pass
58	Protective Earthing – Terminals and Connections	Pass
59	Construction and Layout	Pass

National Deviations

Canadian Deviations for IEC 60601-1, 2nd Ed A1 & A2

Clause	Requirement + Test	Verdict
56	Components and General Assembly	Pass
57	Main Parts, Components and Layout	Pass

U.S. Deviations for IEC 60601-1, 2nd Ed, A1 & A2

Clause	Requirement + Test	Verdict
3	General Requirements	Pass
6	Identification, Marking and Documents	Pass
19	Leakage Currents	Pass
22.4 & 22.7	Moving Parts	Pass
42	Excessive Temperatures	Pass
55	Enclosures and Covers	Pass
56	Components	Pass

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U.S. Deviations for IEC 60601-1, 2nd Ed, A1 & A2 (continued)		
Clause	**Requirement + Test**	**Verdict**
57	Mains Parts	Pass
58	Protective Earthing	Pass
59	Construction and Layout	Pass
60	Separate Power Units	Pass
Australia Deviations for IEC 60601-1, 2nd Ed, A1 & A2		
Clause	**Requirement + Test**	**Verdict**
6.1.g)	Identification, Marking and Documents	Pass
28.2	Support	Pass
42.3	Low Voltage Equipment	Pass
Korean Deviations for IEC 60601-1, 2nd Ed, A1 + A2		
Clause	**Requirement + Test**	**Verdict**
1	Voltage Rating	Pass
2	Plug	Pass
3	Frequency	Pass
Israeli Deviations for IEC 60601-1, 2nd Ed, A1 +A1		
Clause	**Requirement + Test**	**Verdict**
4.7	Supply and Mains Voltages	Pass
36	SI 1011 part 1.2 (IEC 60601-1-2)	Pass
Denmark Deviations for IEC 60601-1, 2nd Ed, A1 + A2		
Clause	**Requirement + Test**	**Verdict**
1	Plugs and Socket Outlets	Pass

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Records Processed under FOIA Request 2016-3415; Released by CDRH on 08/17/2016

Test Report IEC 60601-2-22 (Appendix C4)
Medical electrical equipment
Part 2: Particular requirements for the safety of diagnostic and therapeutic laser equipment
Report Reference No. (b)(4)
PerioLase MVP-7
Millennium Dental Technologies
Date: 10/30/09

IEC 60601-2-22:1995 (Second Edition) for use in conjunction with IEC 60601-1:1988 + A1:1991 + A2:1995

Clause	Requirement – Test	Verdict
6	Identification, Marking and Documents	Pass
32	Light Radiation (Including Lasers)	Pass
49	Interruption of the Power Supply	Pass
50	Accuracy of Operating Data	Pass
51	Protection Against Hazardous Output	Pass
52	Abnormal Operation and Fault Conditions	Pass
55	Enclosures and Covers	Pass
56	Components and General Assembly	Pass
57	Mains Parts, Components and Layout	Pass
59	Construction and Layout	Pass
National Differences		
Australia		
Clause	**Requirement – Test**	**Verdict**
2.1.118	Target Indicating Device	Pass
6.8.101	Medical Surveillance	Pass
Korea		
Clause	**Requirement – Test**	**Verdict**
	Product name, Name and address of Manufacturer, Lot number, Date of manufacture	Pass

Records Processed under FOIA Request 2016-3415; Released by CDRH on 08/17/2016

Constructional Data Report (Appendix C5)
Standard for Safety for Medical Electrical Equipment, Part 1: General Requirements for Safety (UL 60601-1, Issued: 2003-04-25, Ed.:1, Rev: 2006/04/26)
Medical Electrical Equipment – Part 1: General Requirements for Safety General Instruction No. 1; Supplement 1; 1994; Amendment 2 – February 1998; Update No. 2 (CSA C22.2 #601.1, Issue:1990/01/01, R2001)
Medical Electrical Equipment Part 2: Particular Requirements for the Safety of Diagnostic and Therapeutic Laser Equipment (IEC 60601-2-22, Issued: 01/01/1995, Ed: 2)
Report Reference No (b)(4)
PerioLase MVP-7
Millennium Dental Technologies
Date: 10/30/09

The product was tested as indicated below with results in conformance to the relevant test criteria.

Test Description	**UL 60601-1; CSA C22.2 No. 601.1 Clause**	**IEC 60601-2-22 Clause**
Marking Durability	6.1	
Power Input	7	
Residual Voltage in Attachment Plug	15b	
Protective Earthing	18	
Leakage Current	19	
Dielectric Strength	20	
Mechanical Strength – Enclosure	21	
Stability	24	
Normal Temperature	42	
Humidity Conditioning	44.5	
Cleaning	44.7	
Abnormal Operation	52	
Mechanical Strength – Foot Operated Control Devices	56.11	
Laser Emissions Occurring Indicator		32e
Accuracy of Operating Data		50
Possibility of Faulty Operating Conditions		52
Cord Connected and Handheld Foot Operated Devices		56.11b

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA Request 2016-3415; Released by CDRH on 08/17/2016

Evaluation Report (Appendix C6) IEC 60601-1-2:2007 3rd Edition Medical Electrical Equipment - Part 1-2: General Requirements for Basic Safety and Essential Performance - Collateral Standard: Electromagnetic Compatibility - Requirements and Tests Report Reference No. (b)(4) PerioLase MVP-7 Millennium Dental Technologies Date: 2/28/14		
CISPR 11 Group 1		
AC Mains Conducted Emissions	Complies	
CISPR 11 Class A		
Radiated Emissions	Complies	
IEC 61000-4-2		
Electrostatic Discharge Immunity	Met the Performance Criterion	No deviations/degradation of performance
EN 61000-4-4		
Electrical Fast Transient/Burst Immunity	Met the Performance Criterion	No deviations/degradation of performance Deviations, Additions, or Exclusions: None

Records Processed under FOIA Request 2016-3415; Released by CDRH on 08/17/2016

Evaluation Report (Appendix C7) IEC 60601-1-2:2007 3rd Edition Medical Electrical Equipment - Part 1-2: General Requirements for Basic Safety and Essential Performance - Collateral Standard: Electromagnetic Compatibility - Requirements and Tests Report Reference No. (b)(4) PerioLase MVP-7 Millennium Dental Technologies Date: 2/28/14		
CISPR 11 Group 1, IECS-003 and FCC 47CFR Part 15		
AC Mains Conducted Emissions	Complies	
CISPR 11 Class A		
Radiated Emissions	Pass	
IEC 61000-4-2		
Electrostatic Discharge Immunity	Met the performance criterion	No deviations/degradations of performance. EUT exhibits loss of function, can be restored by the operation of the controls by the user in accordance with the manufacturer's instructions.
IEC/EN 61000-4-4		
Electrical Fast Transient/Burst Immunity	Met the performance criterion	No deviations/degradations of performance. EUT exhibits loss of function, can be restored by the operation of the controls by the user in accordance with the manufacturer's instructions.

Records Processed under FOIA Request 2016-3415; Released by CDRH on 08/17/2016

Test Report (Appendix C8)
IEC 60601-1-2:2007 3rd Edition, Class A Emissions, Immunity for Non-Life Supporting Equipment
IEC 61000-3-2(ed.3);am1;am2:2005/11 Electromagnetic Compatibility (EMC) - Part 3-2: Limits - Limits for Harmonic Current Emissions (Equipment Input Current <= 16 A Per Phase)
IEC 61000-3-3(ed.2):2008/06 Electromagnetic Compatibility (EMC) - Part 3-3: Limits - Limitation of Voltage Changes, Voltage Fluctuations and Flicker in Public Low-Voltage Supply Systems, for Equipment with Rated Current <= 16 A Per Phase
Report Reference No (b)(4)
PerioLase MVP-7
Millennium Dental Technologies
Date: 6/30/14

Test Name	**Result**
Radiated Emissions CISPR11 ed5.1 (with A1:2010) Class B	Complies
AC Mains Conducted Emissions CISPR11 ed5.1 (with A1:2010) Class B	Complies
Harmonics IEC 61000-3-2 ed3.0 (with A1:2008+A2:2009)	Complies
Flicker IEC 61000-3-3 ed2.0 (2008-06)	Complies
Electro-Static Discharge Immunity Test IEC 61000-4-2 ed2.0 (2008-12)	Complies
Radiated, Radio-Frequency, Electromagnetic Immunity IEC 61000-4-3 ed3.0 (with A1:2007:A2:2010)	Complies
Electrical Fast Transient/Burst Immunity Test IEC 61000-4-4 ed3.0 (2012-04)	Complies
Immunity to Surges IEC 61000-4-5 ed2.0 (2005-11)	Complies
Conducted, Radio-Frequency, Electromagnetic Immunity Test IEC 61000-4-6 ed2.0 (with A1:2004+A2:2006)	Complies
Power Frequency Magnetic Field Immunity Test IEC 61000-4-8 ed2.0 (2009-09)	Complies
Voltage Dips/Interruptions Immunity Test IEC 61000-4-11 ed2.0 (2004-03)	Complies
No additions, deviations, or exclusions have been made from the standards.	

(b)(4)3rd Party Testing

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(b)(4) Failure Mode and Effects Analysis

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APPENDIX E
PERIODONTAL REGENERATION - HISTOLOGY STUDY SUMMARY

SUMMARY

Eight (8) patients treated with the LANAP® protocol (Appendix A, pages 6-2 to 6-5) using the PerioLase Nd:YAG laser provided twelve (12) treated teeth that were scheduled for extraction. After nine (9) months of healing *en bloc* biopsy extractions were evaluated histologically to assess periodontal wound healing. Two (2) teeth were lost during processing, four (4) healed via long junctional epithelium, one (1) showed new attachment, and five (5) teeth demonstrated periodontal regeneration with new cementum, periodontal ligament, and alveolar bone.

BACKGROUND

Periodontitis is an infectious disease that progressively destroys the alveolar bone, the periodontal ligament, and the root cementum that attach the teeth to the bone. Destruction of this attachment apparatus results in the loss of teeth. The ultimate aim of periodontal regeneration techniques is to induce or guide healing to regenerate the morphology back to its original configuration. In order to evaluate a regeneration technique experimentally, a notch is made on the root surface at the bottom of a periodontal pocket to provide a histological landmark for the apical extent of the destruction. True periodontal regeneration is then defined by histological evidence of new bone, periodontal ligament, and cementum appearing above the notch on a previously diseased root surface.[1]

Kao, Nares, and Reynolds (2015)[2] is the most recent of a long series of systematic reviews of published methods to achieve periodontal regeneration.[3-12] Current approaches include Demineralized Freeze-Dried Bone Allograft (DFDBA), Guided Tissue Regeneration (GTR), bone fill with Enamel Matrix Derivative (EMD), Recombinant Human Platelet-Derived Growth Factor BB (rhPDGF-BB), and Open Flap Debridement (OFD). Kao *et al.* have included a new category of regenerative approaches termed Laser-Assisted Regeneration (LAR), which is identified specifically as the Millennium Dental Technologies LANAP® protocol using the PerioLase pulsed Nd:YAG Dental Laser System. Based on the review of two peer-reviewed studies of human histology [13,14] following LANAP® Kao *et al.* conclude,

> "Using the Nd:YAG laser with this [LANAP] procedure, periodontal regeneration is achievable on a previously diseased root surface."

Data from the first human histology study post-LANAP® by Yukna, *et al.* (2007)[13] were submitted to the FDA in 2003. Healing at 3 months clearly showed new attachment and suggestions of regeneration (reference [13] Figs. 2 & 3). Subsequently, the FDA granted marketing clearance (K030290) on July 26, 2004 for the claim: "Laser assisted new attachment procedure (cementum-mediated periodontal ligament new-attachment to the root surface in the absence of long junctional epithelium)." The second, more recent study by Nevins *et al.* (2012),[14] looked at healing 9 months following LANAP®. They conclude, "This report provides evidence that LANAP® therapy can induce periodontal regeneration." These data from the Nevins human histology study[14] are presented below to support the clinical outcome claim:

> "Periodontal regeneration – true regeneration of the attachment apparatus (new cementum, new periodontal ligament, and new alveolar bone) on a previously diseased root surface when used specifically in the LANAP® Protocol."

STUDY DATA

The purpose of this 510(k) application is to present histological evidence of true periodontal regeneration to support the proposed clinical outcome claim. Images of study specimens are provided for the reviewer's assessment. Some of these images are unpublished. Methods and clinical results are summarized. Details are available in the peer-reviewed article attached[14] (APPENDIX F).

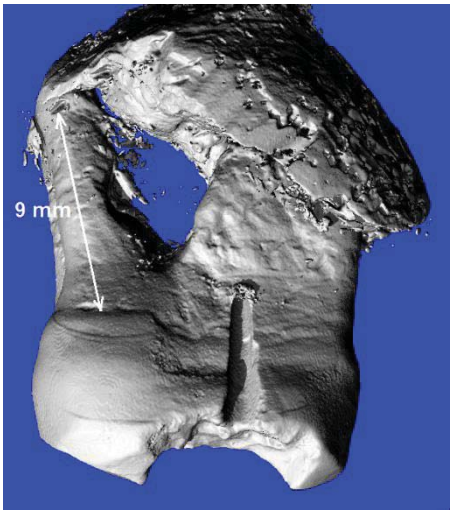
Methods

This was a private practice, single-center, prospective clinical study with enrollment completed from May 1 through June 30, 2010. Subjects provided informed consent according to the Declaration of Helsinki of 1975, as revised in 2000. A total of 12 periodontal defects were identified in 8 subjects with advanced periodontitis. Eligibility required subjects to be between the ages of 18 and 70 years and have at least 1 tooth diagnosed and prescribed for extraction with a probing depth ≥ 7 mm and radiographic suggestion of a 4-mm or deeper intrabony defect. Subjects were excluded from the study if they had congenital or metabolic bone disorders, immunosuppressive therapy, or disease that may affect wound healing; were current smokers (within 6 months of entry into the study); or were pregnant or planning pregnancy during the course of the study. In addition, subjects with a history of active periodontal surgical treatment or scaling and root planning during the past 12 months were excluded.

Full-mouth clinical measurements were collected prior to beginning the surgical visit. The LANAP procedure uses the PerioLase MVP-7 pulsed Nd:YAG Dental Laser System. The laser is first used at a setting of 4.0 W, 100-µs pulse duration, and 20 Hz. It is passed from the gingival margins to the base of the pocket parallel to the root surface and moved laterally and apically to remove the diseased pocket epithelium and decontaminate the pocket. This is accomplished for all surfaces of the pockets for all teeth in a single arch. The teeth are then aggressively scaled and root planed with piezo ultrasonic instrumentation. A second pass with settings of 4.0 W, 650-µs pulse duration, and 20 Hz produces a stable fibrin clot that helps close the wound and enable healing. (See Appendix A, pages 6-2 to 6-5, with detailed LANAP® protocol.)

At 9 months post-LANAP clinical measurements were collected, then an *en bloc* biopsy of the study tooth was performed. Biopsy sites were reconstructed with regenerative procedures in preparation for implant placement and subsequent prosthetic reconstruction with implant-supported prostheses. Biopsy specimens were stored in 10% formalin.

Specimens were imaged with a high-resolution microcomputerized tomography (micro-CT) system to verify notch location (Right). Then nondemineralized ground sections were stained and examined with brightfield and polarized light microscopy. Selected specimens were prepared for scanning electron microscopy.



Micro-CT scan of Patient 6, tooth 14. The notch location is verified on the distal tip of the root 9 mm from the CEJ. The vertical trough made after the biopsy identifies the palatal surface.

Clinical Results

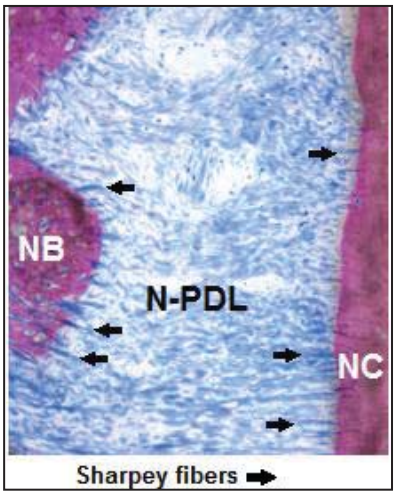
The mean probing depth (PD) of the 12 study sites at enrollment was 10.4 mm. This was reduced to 5.0 mm at 9 months following LANAP. Mean clinical attachment level (CAL) gained 3.8 mm going from 11.2 mm at baseline to 7.4 mm at 9 months (Table A-1). Overall there were 444 sites with 5 mm or greater PD at baseline. Eighty-eight percent (88%) improved at 9 months, 9% showed no change, and 3% had an increase in PD. Seventy-four percent (74%) gained attachment level, 17% showed no change, and 9% lost attachment.

Table A-1. Eight (8) patients provided 12 teeth that were treated with the LANAP protocol and then extracted at 9 months post-treatment. Each experimental site had a Probing Depth (PD) ≥ 8mm and Clinical Attachment Level (CAL) loss of ≥ 8 mm. All sites demonstrated PD reductions and CAL gains at 9 months. Histology results for each site are also listed. The far right column lists the distance from the cementoenamel junction (CEJ) to the notch as measured with a micro-CT scanner. Values are in millimeters (mm). LJE: Long Junctional Epithelium.

Patient #	Tooth #	Baseline		9 months		PD reduction	CAL gain	Histology results	Notch to CEJ
		PD	CAL	PD	CAL				
1	21	9	9	3	7	6	2	**Regeneration**	8
2	25	8	10	3	8	5	2	LJE	9
2	29	14	16	4	9	10	7	**New Attachment**	11
3	21	10	11	7	8	3	3	LJE	8
3	22	10	10	5	7	5	3	LJE	8
4	4	10	12	8	10	2	2	LJE	9
5	19	16	16	6	7	10	9	**Regeneration***	7
5	22	12	12	4	7	8	5	**Regeneration**	8
5	29	9	9	6	7	3	2	Not available	
6	14	9	11	4	6	5	5	**Regeneration***	9
7	30	8	8	4	7	4	1	Not available	
8	15	10	10	6	6	4	4	**Regeneration***	7
Mean		10.4	11.2	5.0	7.4	5.4	3.8		
S.D.		2.43	2.55	1.60	1.16	2.64	2.38	* Furcation involvement	

Histology Results

Two teeth splintered during histological preparation and were not available for microscopic evaluation. Five of the remaining ten sites (50%) healed coronal to the notch with true periodontal regeneration, demonstrating new cementum (NC), new periodontal ligament (N-PDL), and new alveolar bone (NB) with inserting Sharpey's fibers forming functional reattachments.



Three teeth demonstrating regeneration coronal to the notch also presented with loss of attachment within furcations. These areas demonstrated new bone, new ligament, and new cementum as well.

Four (4) teeth healed via long junctional epithelium (LJE) and one (1) tooth demonstrated new cementum and reattachment apical to the notch. The five regeneration cases, the new attachment case, and three cases healing with LJE are presented below.

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** Reprints included in Appendix F

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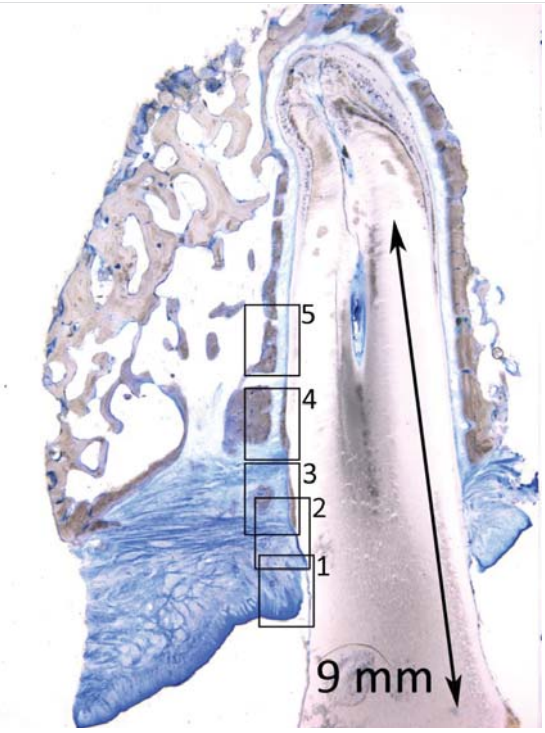

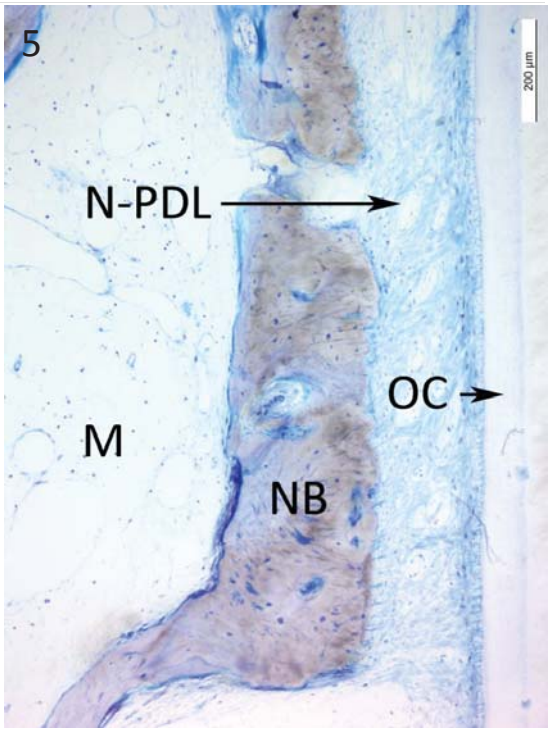

PATIENT 6, TOOTH 14 - REGENERATION

LEFT COLUMN: Maxillary left first molar presented with an initial CAL of 11 mm, a Grade III furcation, and a mesial intrabony defect. The 9-month post-treatment radiograph suggests bone fill. CENTER: Panoramic view showing bone fill and periodontal regeneration. CAL gain at 9 months was 5 mm. RIGHT: The close-up of INSET 5 demonstrates new alveolar bone (NB) and new periodontal ligament (N-PDL) adjacent to the old cementum (OC). INSETs 1-4 are shown on the following pages. M: bone marrow.

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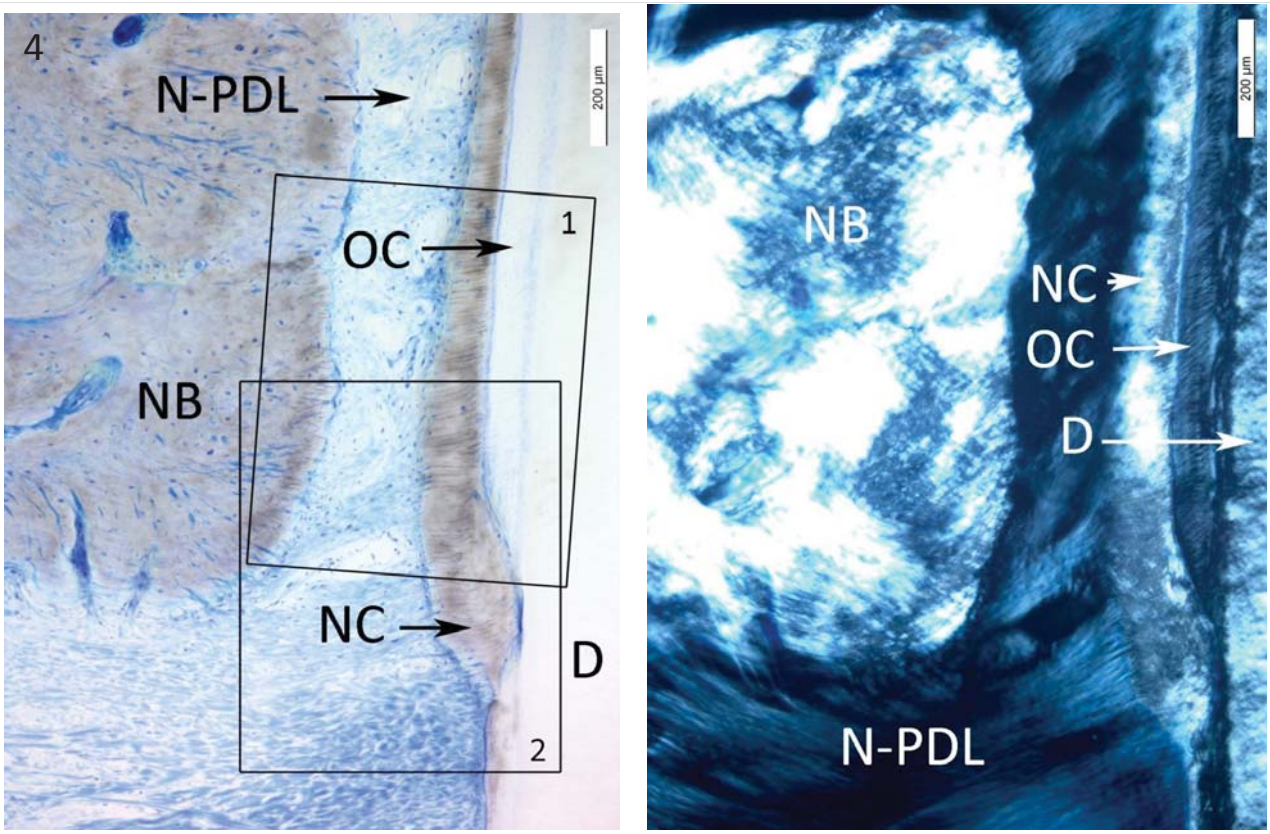

6-14 REGEN. LEFT: Several mm's coronal to the calculus notch (INSET 4) is a distinct layer of new cementum (NC) adjacent to the root dentin (D). Higher magnification views appear on the next page. RIGHT: Polarized light microscopy enables visualization of bundles of collagen fibers connecting the new bone to the new cementum. See the next page for enlarged box 2, showing Sharpey's fibers and cementoblasts on the surface of the new cementum.

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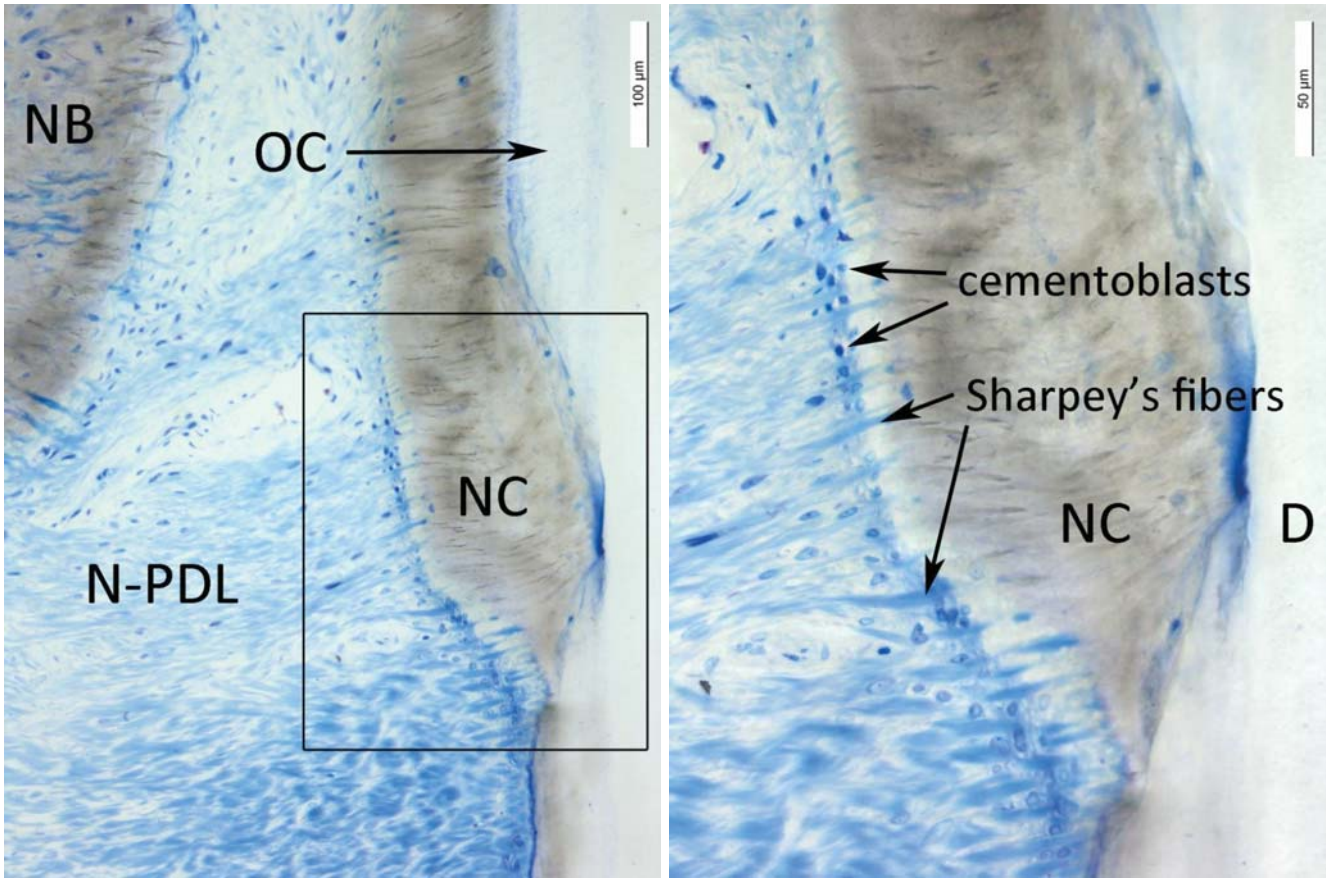

6-14 REGEN

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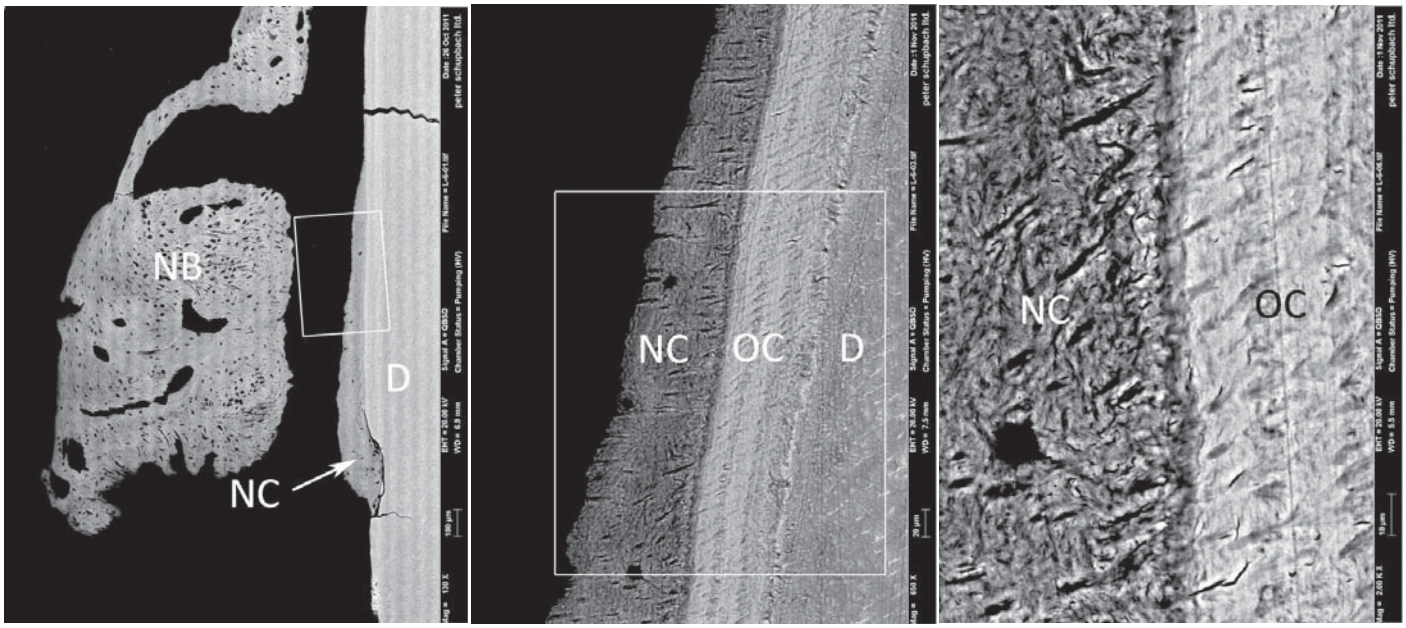

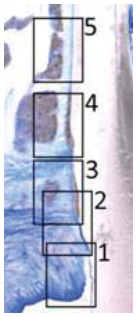

6-14 REGEN. Backscatter electron microscopy of INSET 4, located approximately 4 mm coronal to the notch confirms the histologic assessment. Layers of root dentin (D), old cementum (OC), and new cementum (NC) can be well visualized.

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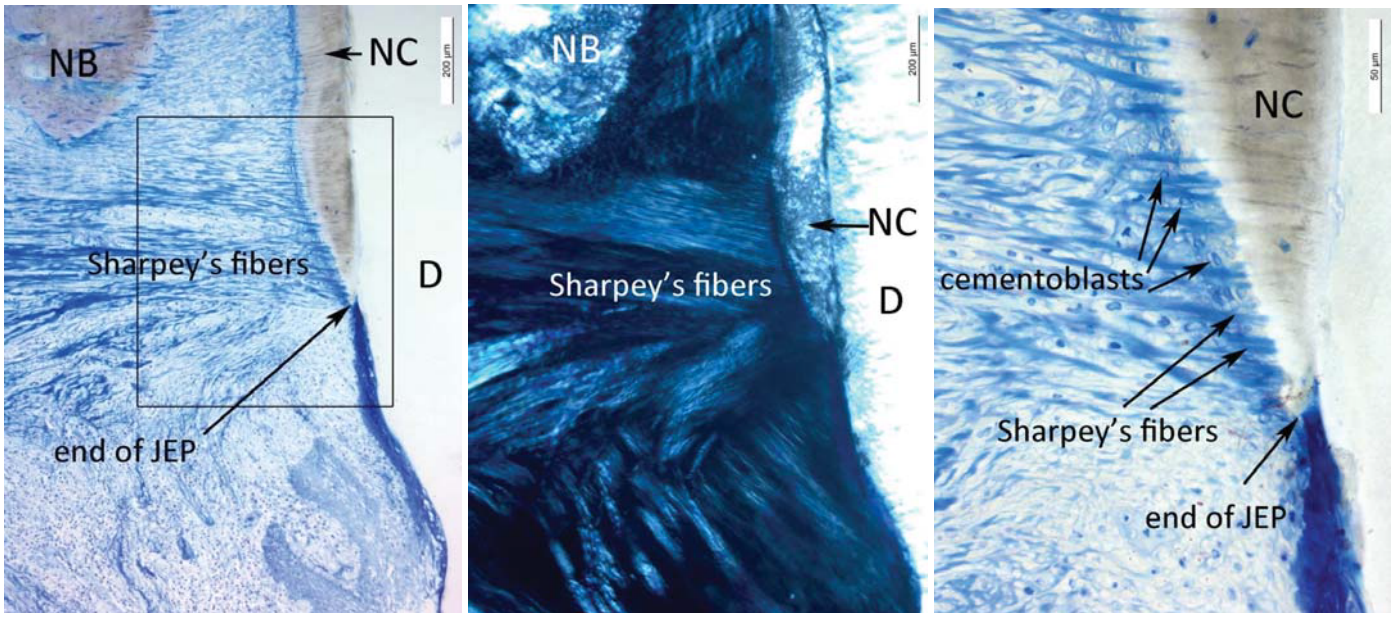

6-14 REGEN. LEFT: The supracrestal environment has regenerated to its natural state with Sharpey's fibers inserting into the new cementum just apical to the junctional epithelium (JEP).
CENTER: Polarized light reveals fascicles of birefringent collagen fibers.
RIGHT: High magnification of INSET showing cementoblasts and Sharpey's fibers at the junction with the JEP.

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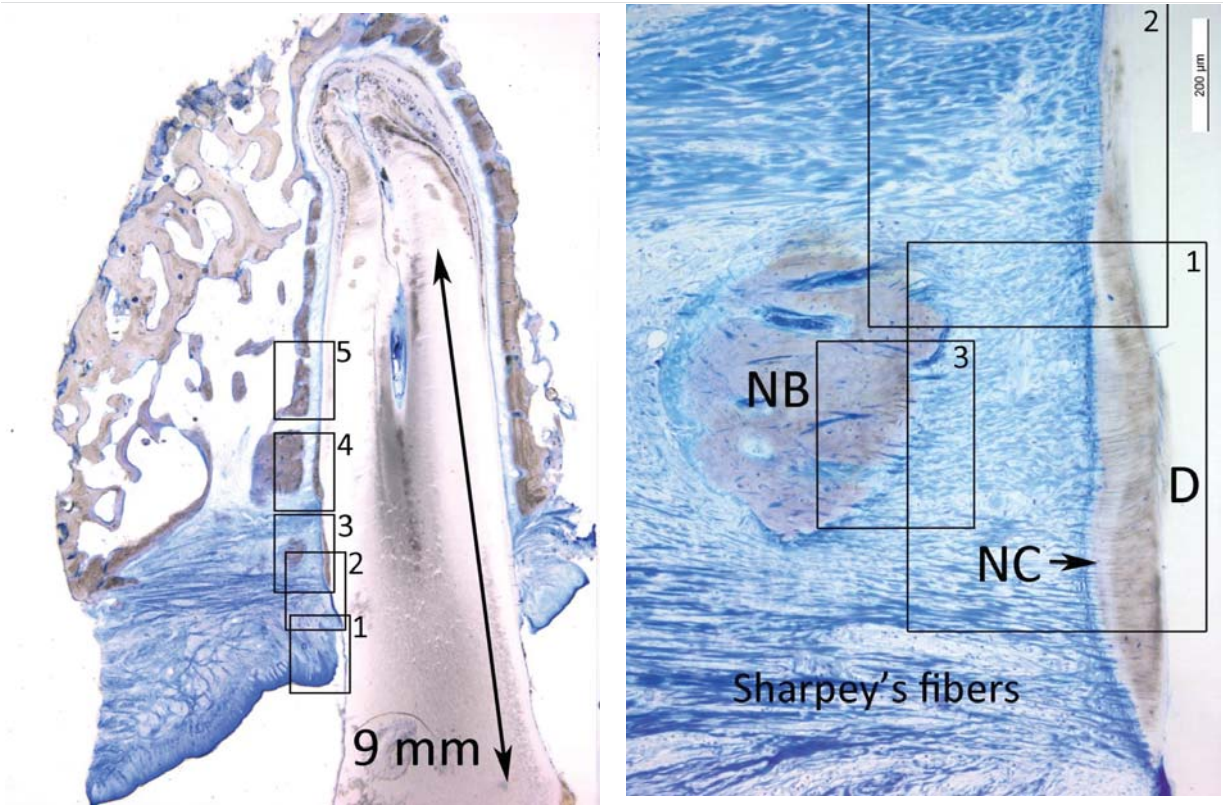

6-14 - REGENERATION. LEFT: Global view. RIGHT: INSET 3 shows continued regeneration of the supracrestal environment 9 months following treatment. An island of new bone and a thick layer of new cementum with interconnecting fibers of the PDL establishes a new level of attachment and presents a barrier to JEP migration. High magnification views appear on the next page.

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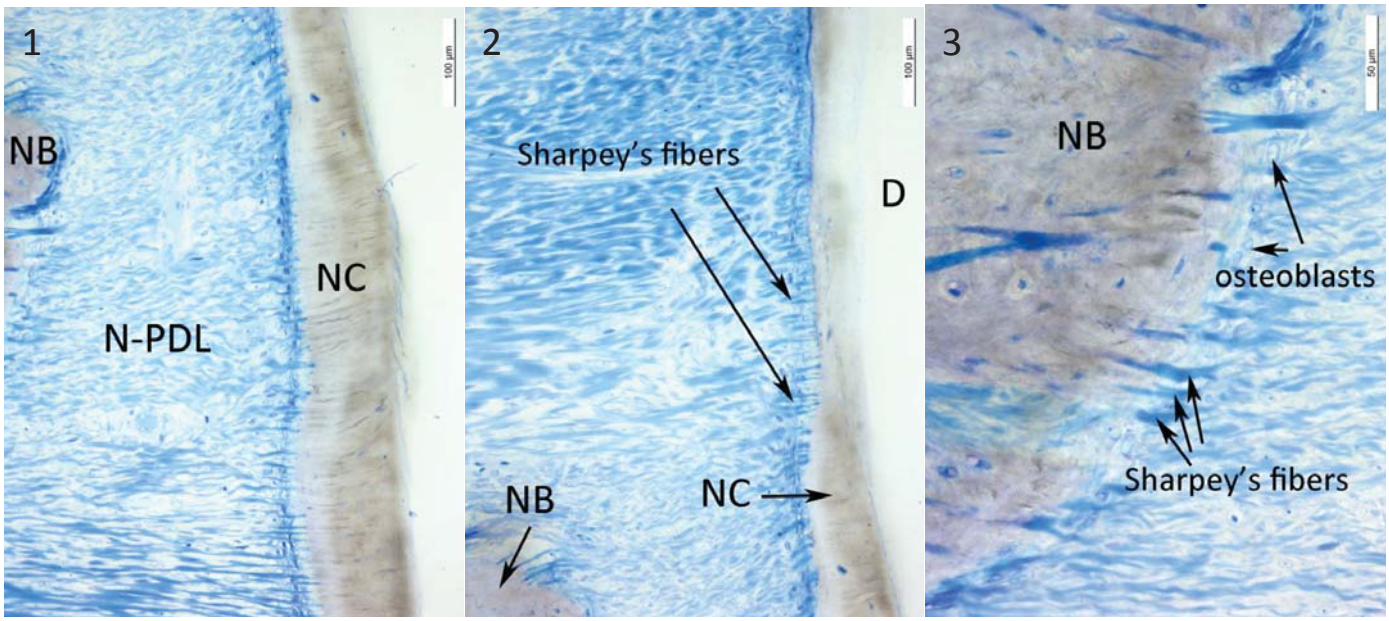

6-14 REGEN

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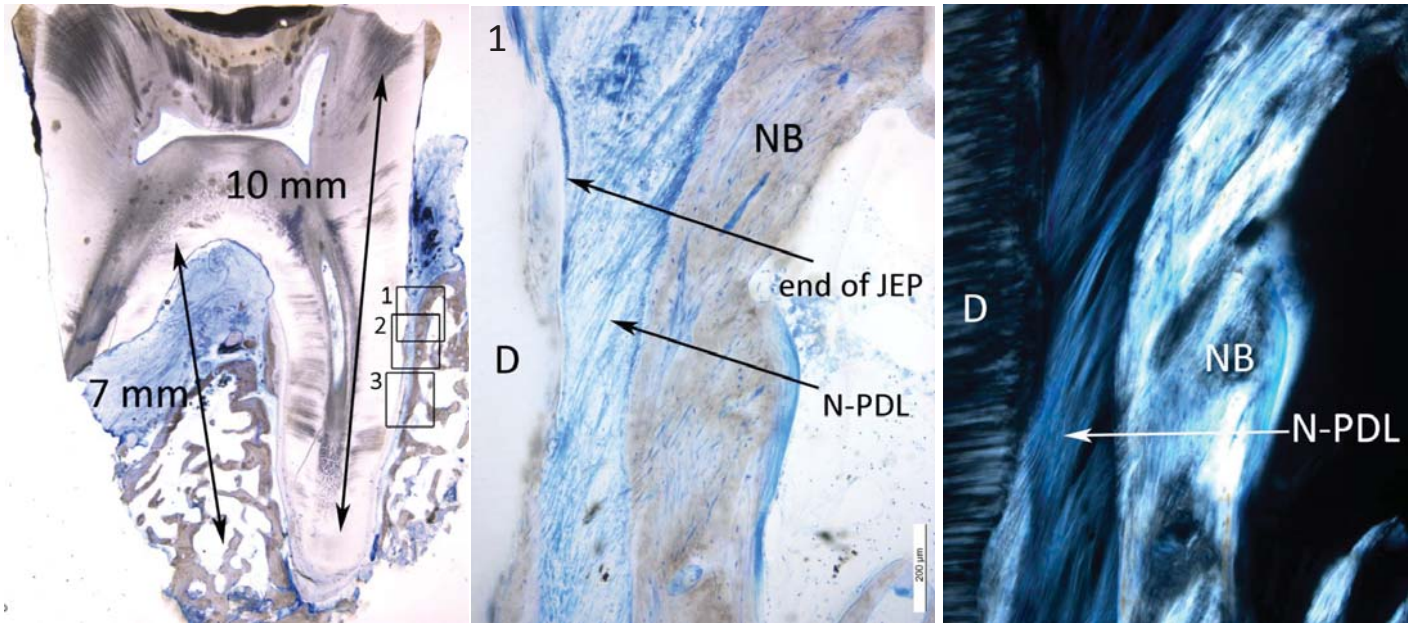

PATIENT 5, TOOTH 19 - REGENERATION

Mandibular left first molar presented at baseline with a 16-mm deep pocket and CAL of 16 mm with Grade II furcation involvement. CAL showed a 9 mm gain at 9 months. There is new cementum, PDL, and bone along the apical root surface to the level of the crestal ridge. The JEP terminates at the location of new cementum anchored to new bone with fibers of the regenerated PDL. A high-magnification view of INSET 2 is on the next page.

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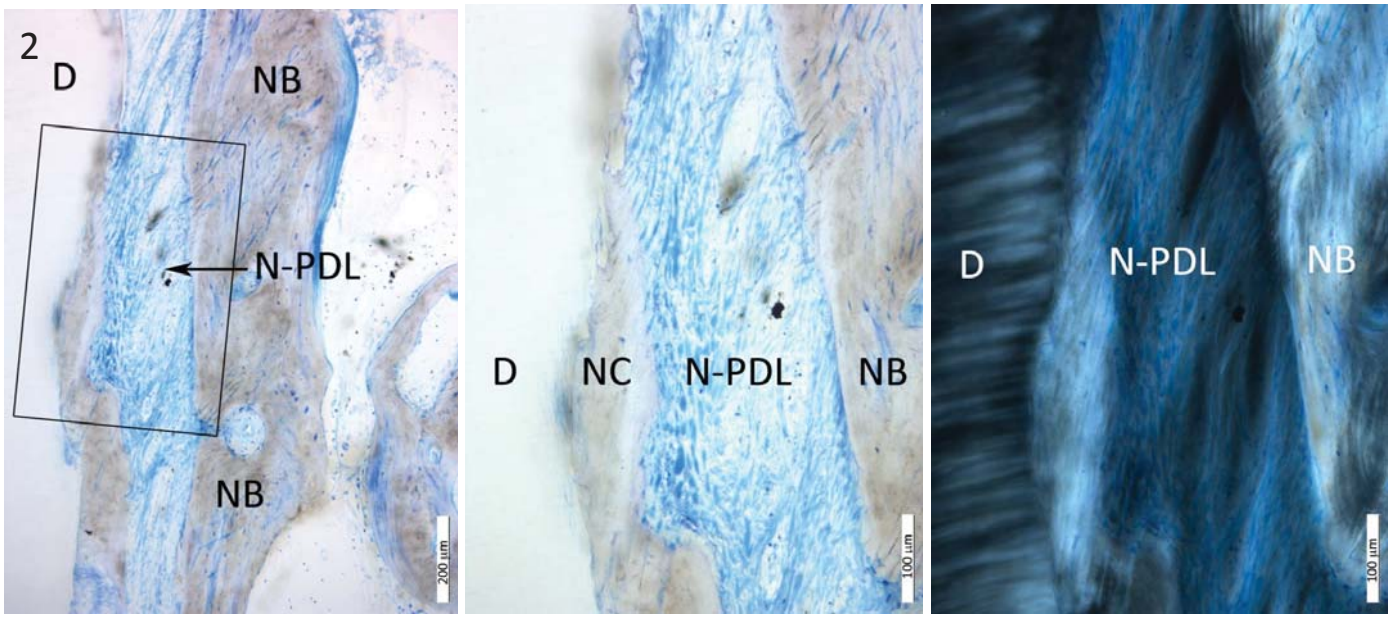

5-19 REGEN

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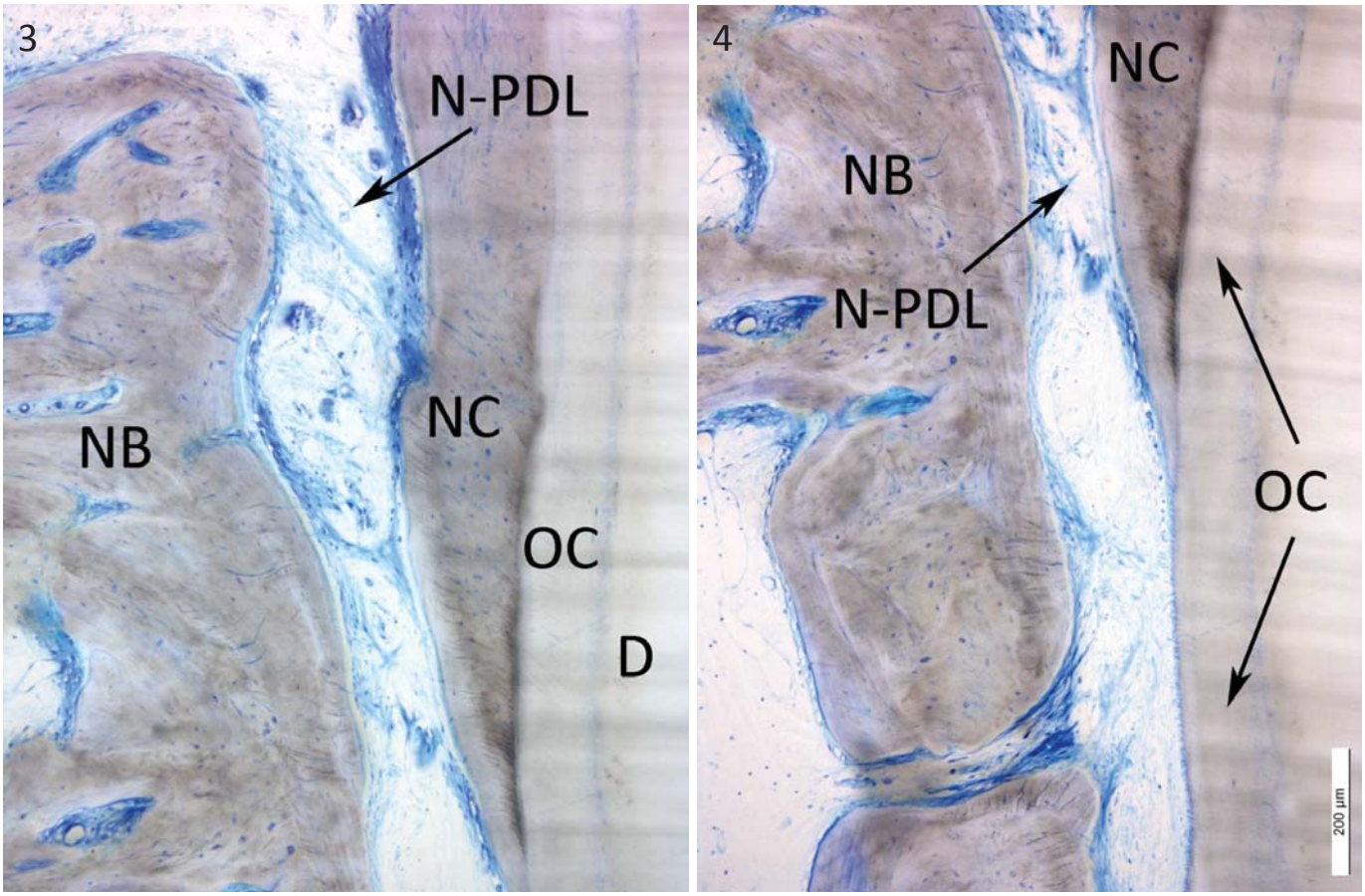

5-19 REGEN

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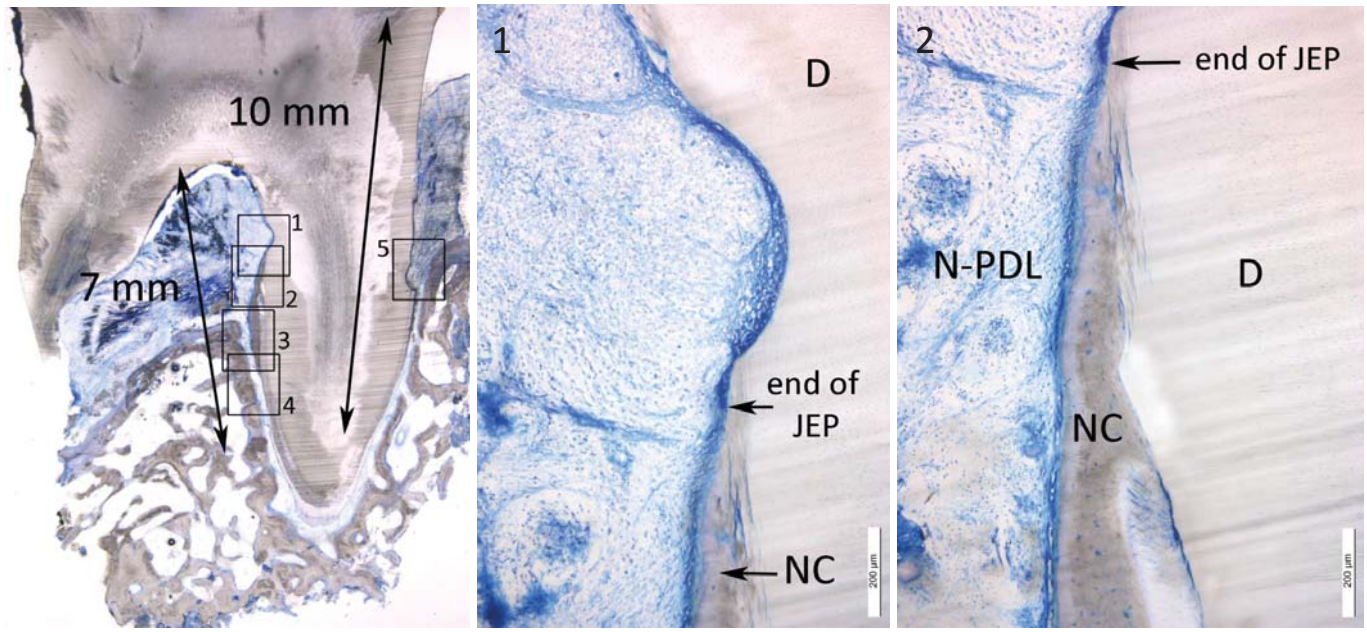

5-19. REGEN. Tissue regeneration was also observed coronal to the notch along the mesial root surface and within the furcation. LEFT: The notch measurement is from CEJ not fornix of furcation (Grade III) as illustrated. MIDDLE: The enlarged view shows the end of JEP and a layer of new cementum, new bone, and new PDL. INSETs 3, 4, and 5 are on the following pages.
Periodontal regeneration coronal to the calculus notch was confirmed for two other teeth presenting with furcation involvement. Although none of the furcations closed or were reduced in grade, they demonstrated significant CAL gain and histologic assessment of regeneration.

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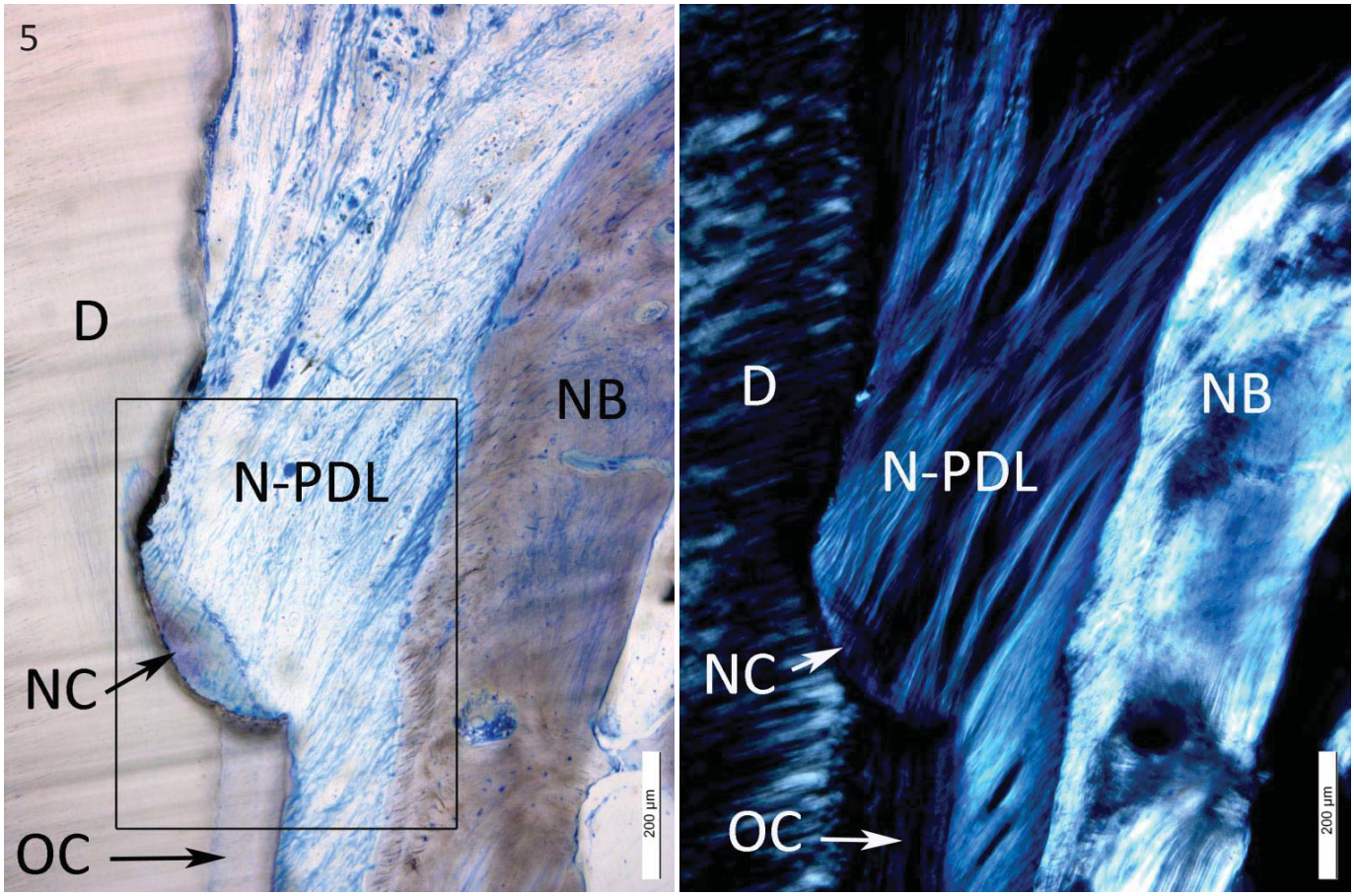

5-19 REGEN

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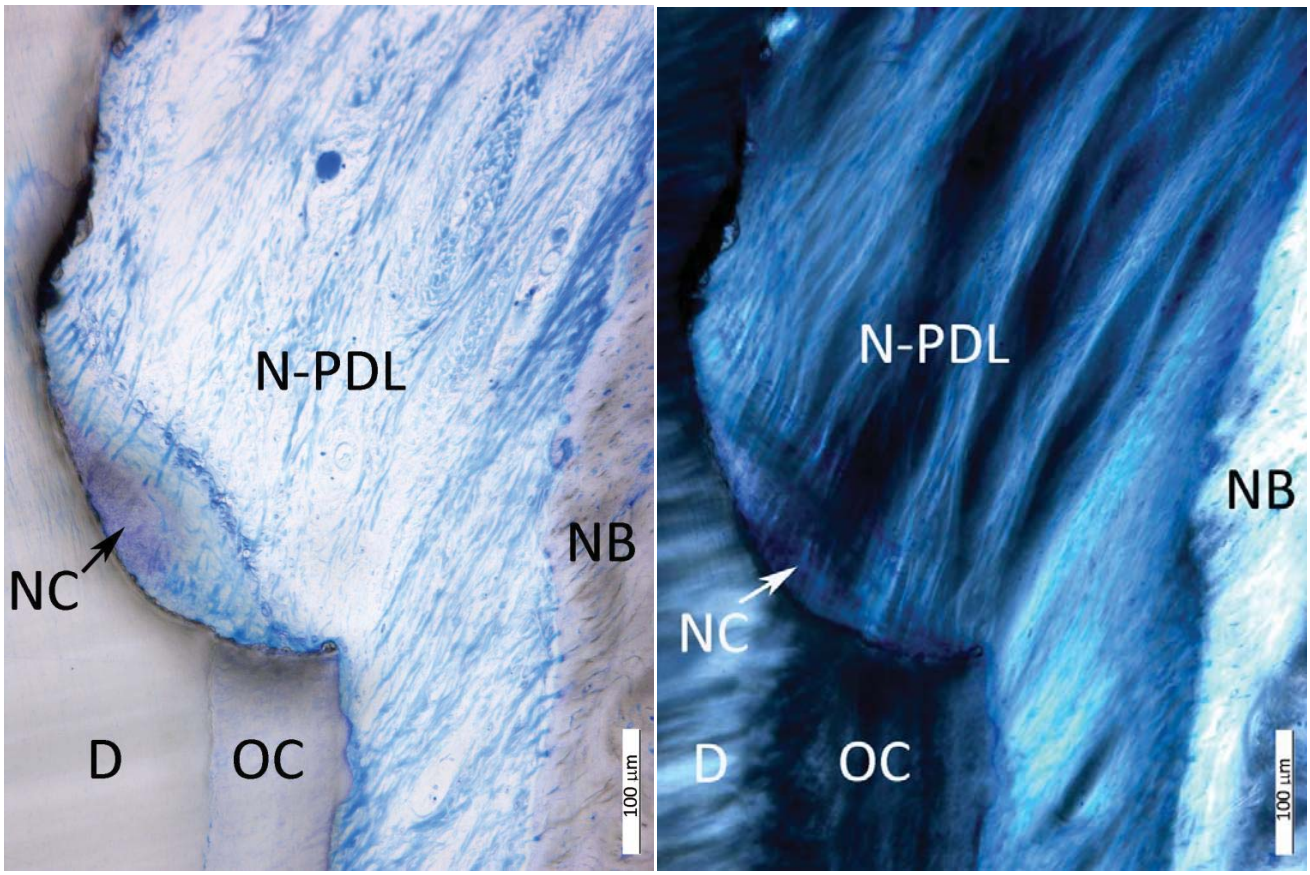

5-19 REGEN. Area marked NC shows ongoing formation of new cementum with imbedded Sharpey's fibers.

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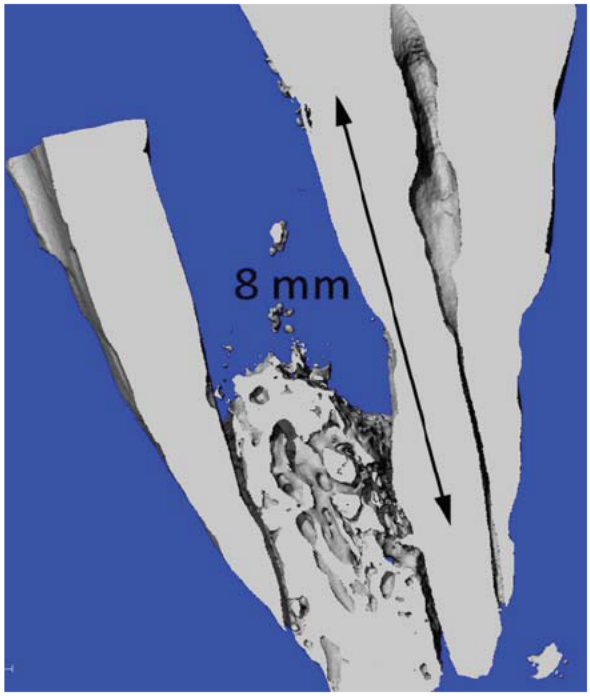

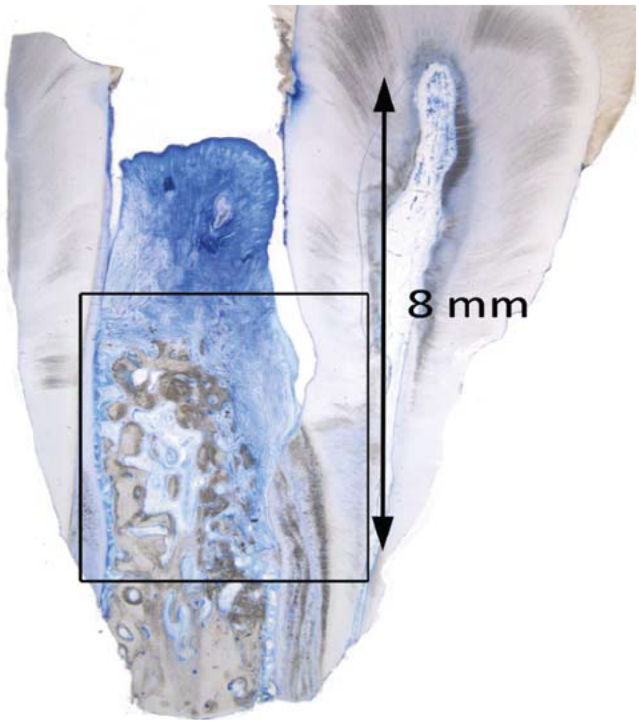

PATIENT 1, TOOTH 21 - REGENERATION

Mandibular left first premolar. LEFT: Micro-CT scan with 8-mm notch measurement from the cementoenamel junction RIGHT: CAL went from 9 mm to 7 mm at 9 months. Note bone fill of the defect proximal to the previously diseased root surface. There is evidence of regeneration coronal to the notch and cementogenesis is easily visible at and coronal to the notch. The epithelium was limited coronal to the regeneration (end of JEP, next page). Enlarged views of the boxed area appear on the following two pages. OB: old bone.

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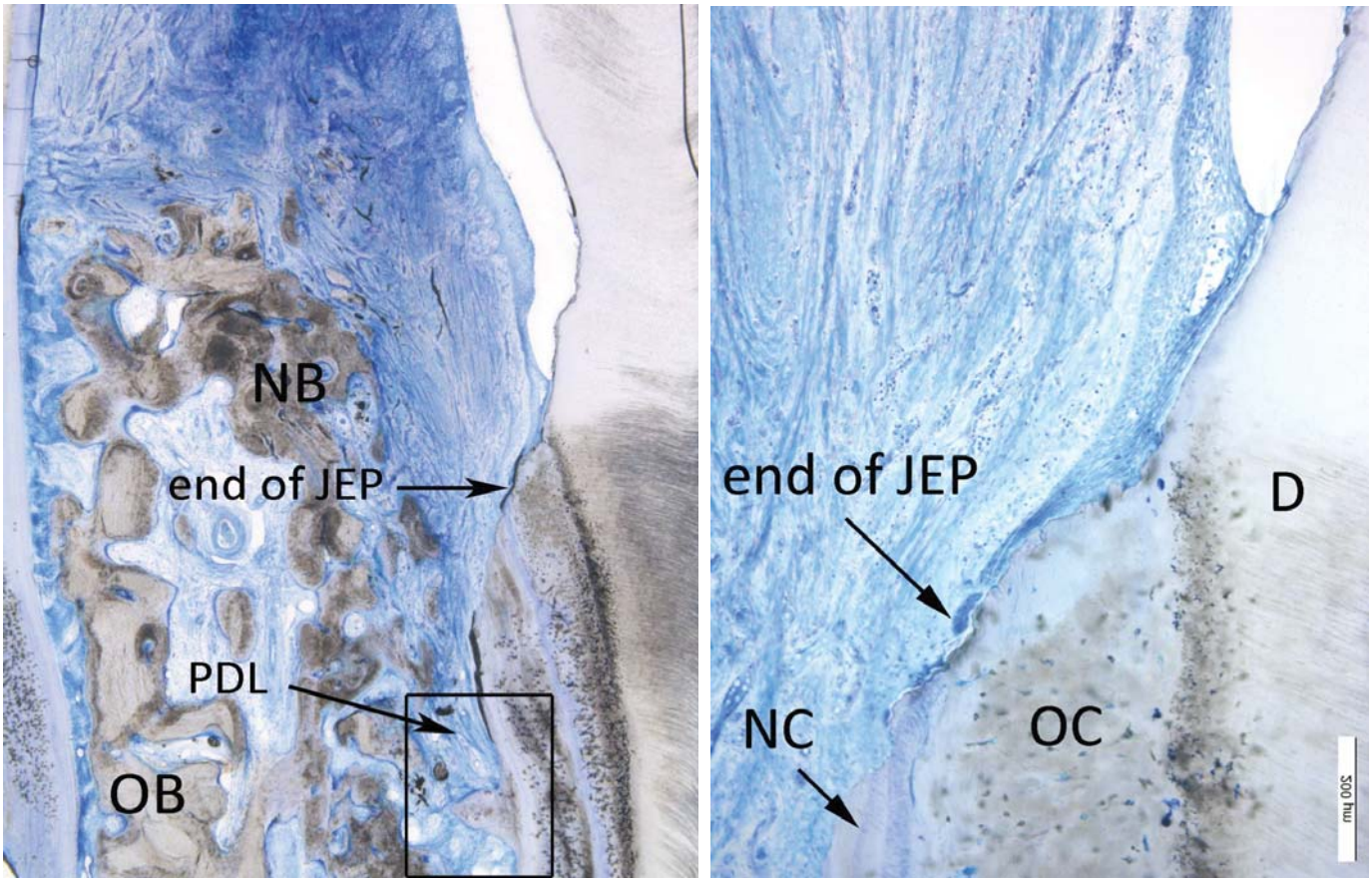

1-21 REGEN

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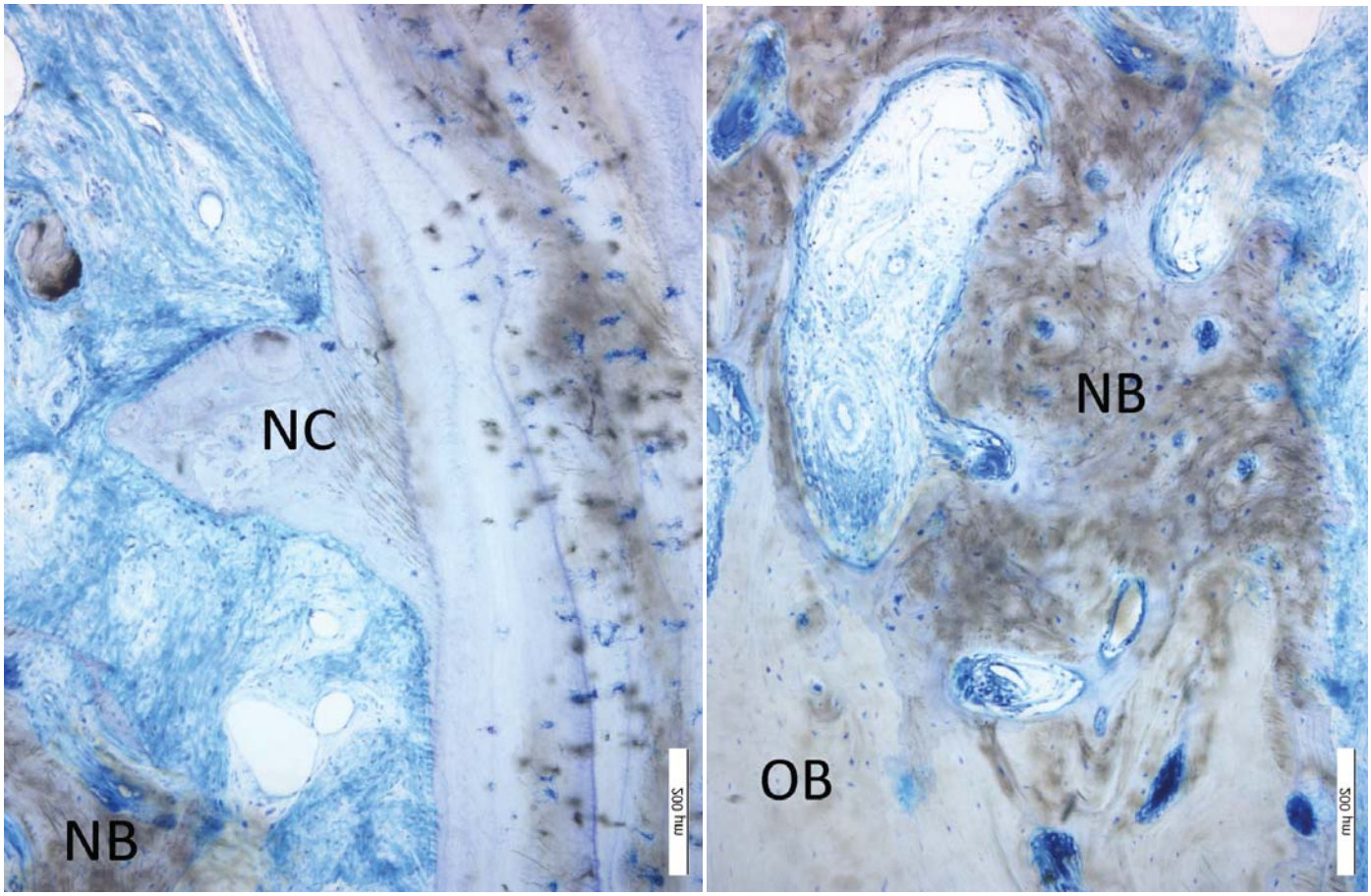

1-21 REGEN

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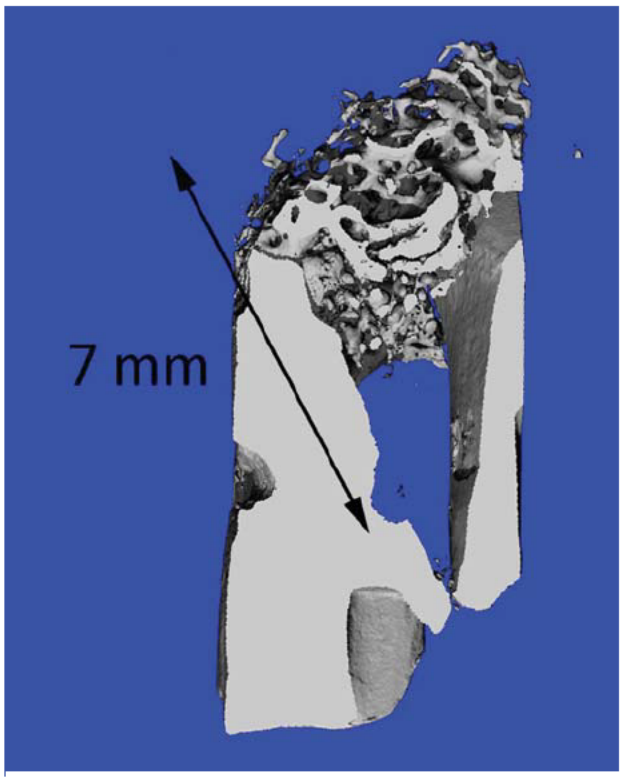

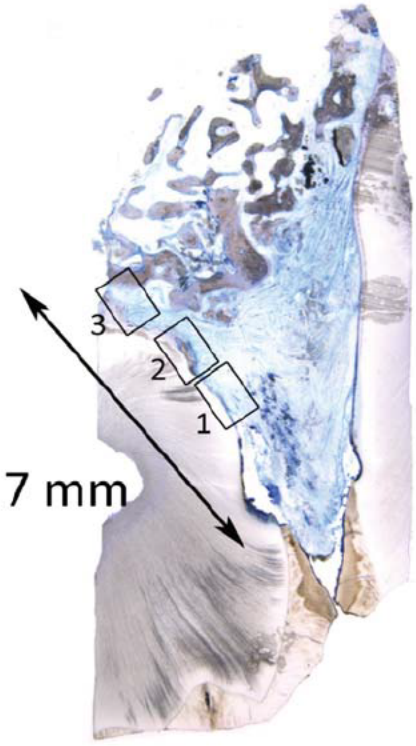

PATIENT 8, TOOTH 15 - REGENERATION

Maxillary left second molar with an attachment loss of 10 mm that was reduced by 4 mm at 9 months. LEFT: Micro-CT scan with 7-mm measurement from the CEJ (bottom) to the notch (not shown). The root surface defect at the CEJ is a marking made at the time of biopsy for orientation. RIGHT: Supracrestal environment showing the end of the JEP (INSET 1 on the next page), new cementum, Sharpey's fibers, new PDL, and new bone (INSETs 2 & 3).

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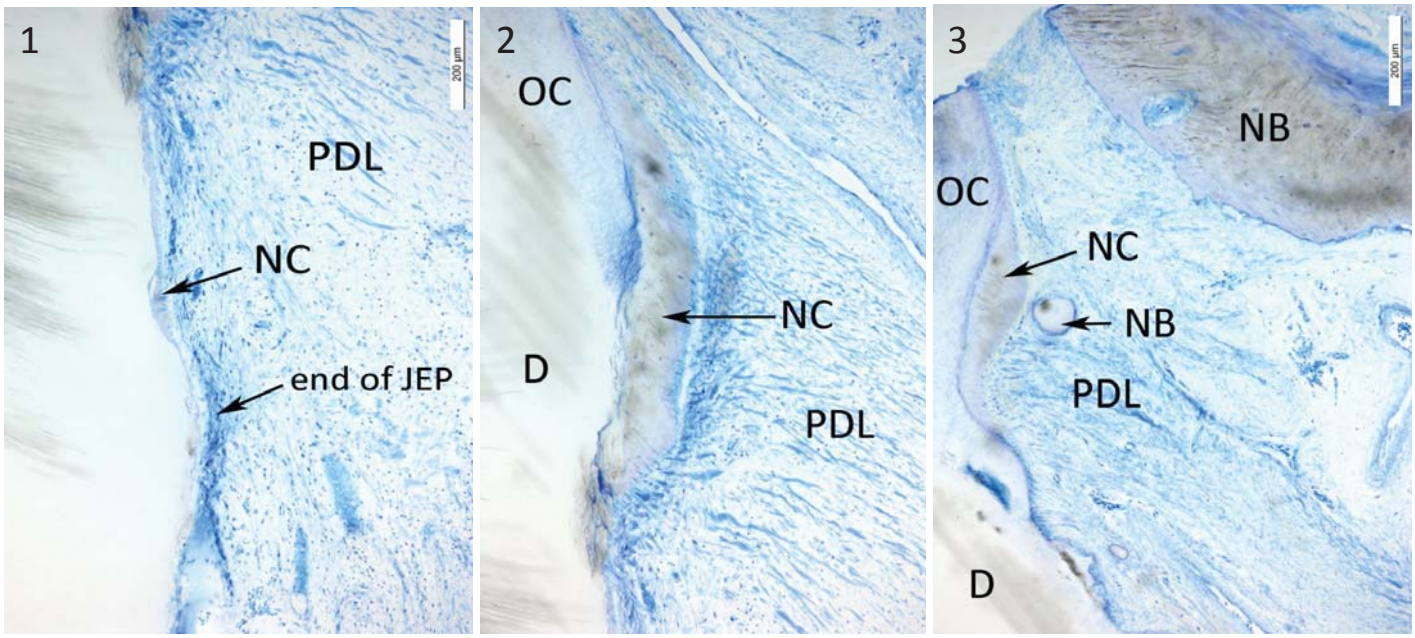

8-15 REGEN

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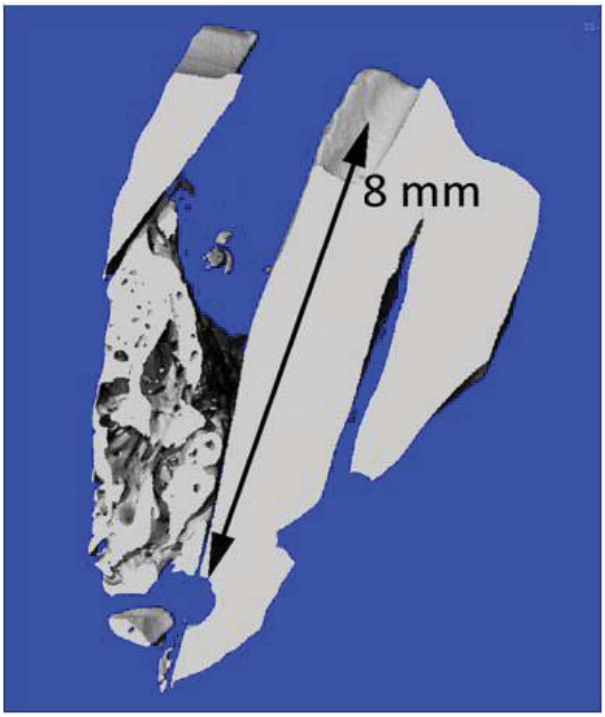

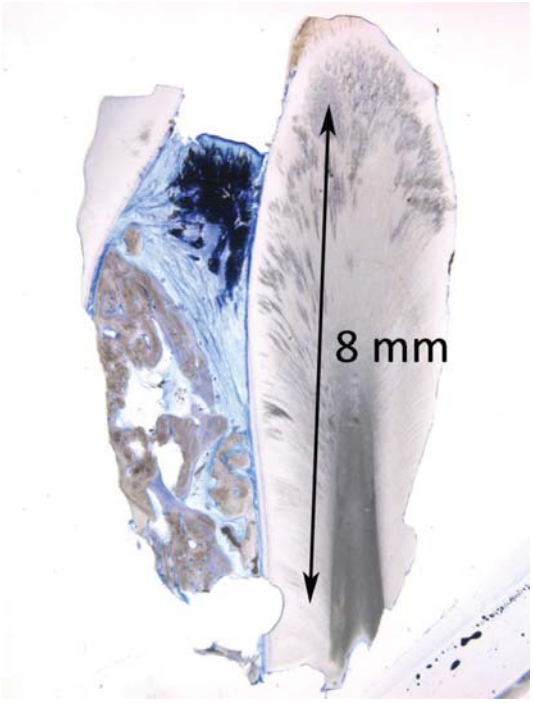

PATIENT 5, TOOTH 22 - REGENERATION

Maxillary left cuspid presented with a 12 mm pocket and a CAL of 12 mm. At 9 months CAL was improved by 5 mm, to 7 mm. Histology demonstrates a substantial amount of new bone and new PDL coronal to the notch. The authors[14] comment, "The lack of new cementum is questionable. We feel comfortable with this result, although not as dramatic." A high-magnification view appears on the next page.

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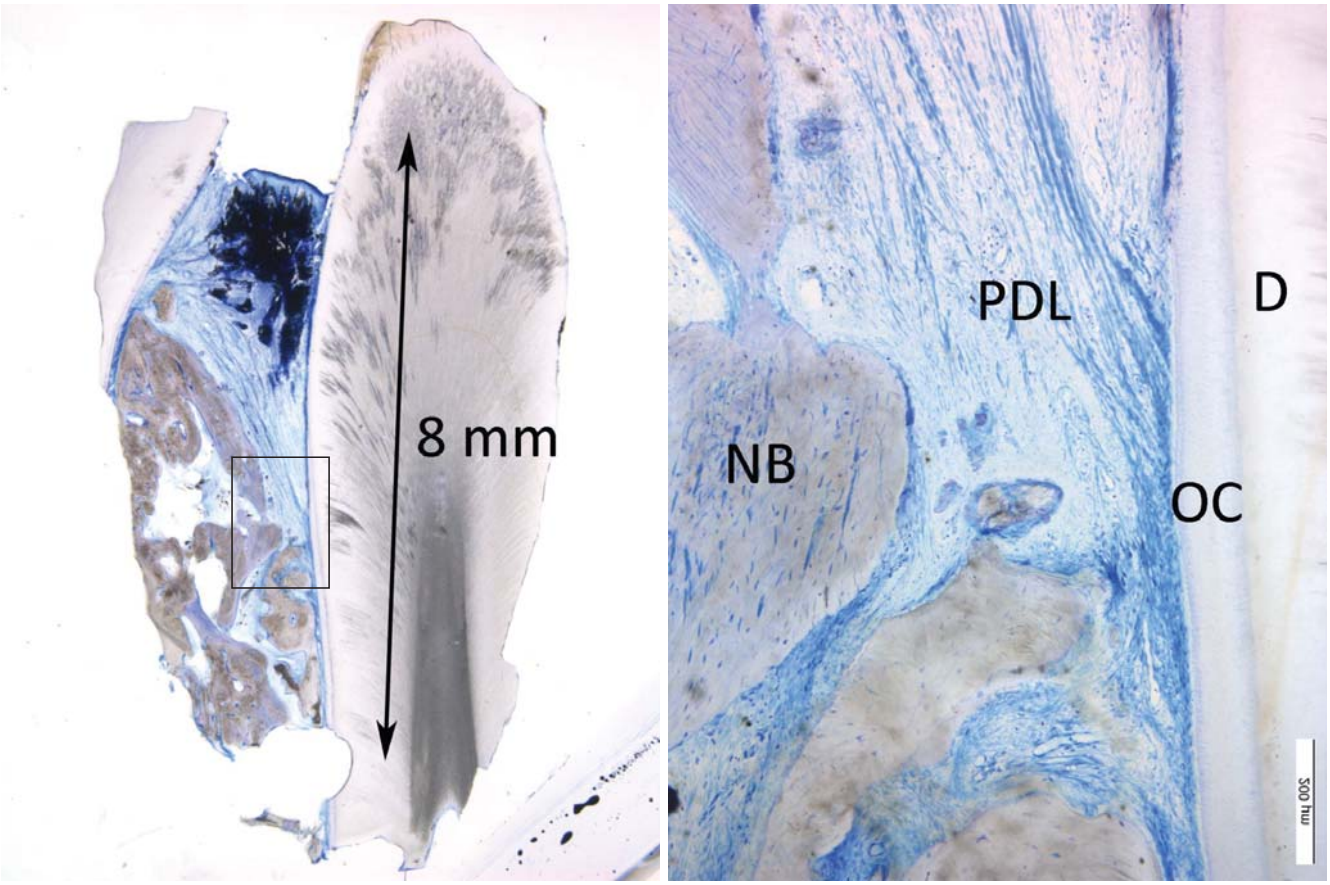

5-22 REGEN

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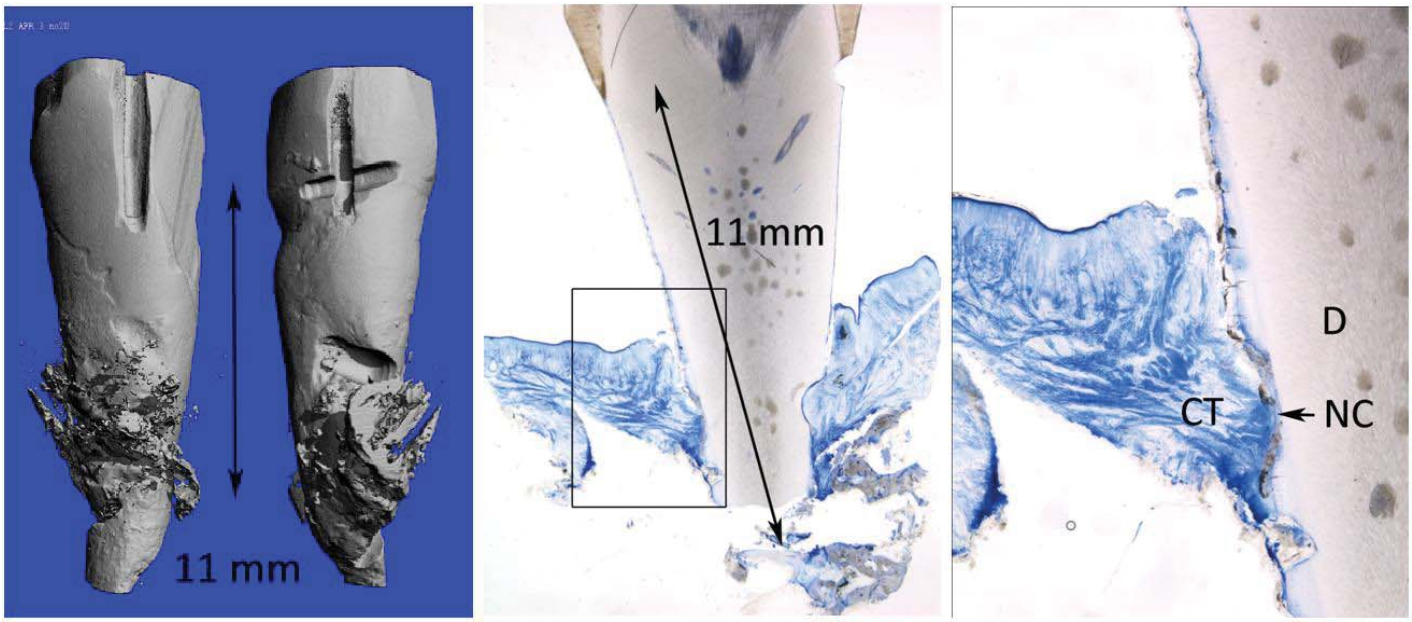

PATIENT 2, TOOTH 29 - NEW ATTACHMENT

Mandibular right second premolar CAL went from 16 mm to 9 mm, a 7 mm gain in attachment level. There is clearly new attachment and the micro-CT is suggestive of regeneration, but the fracture during processing only allows identification of new attachment.

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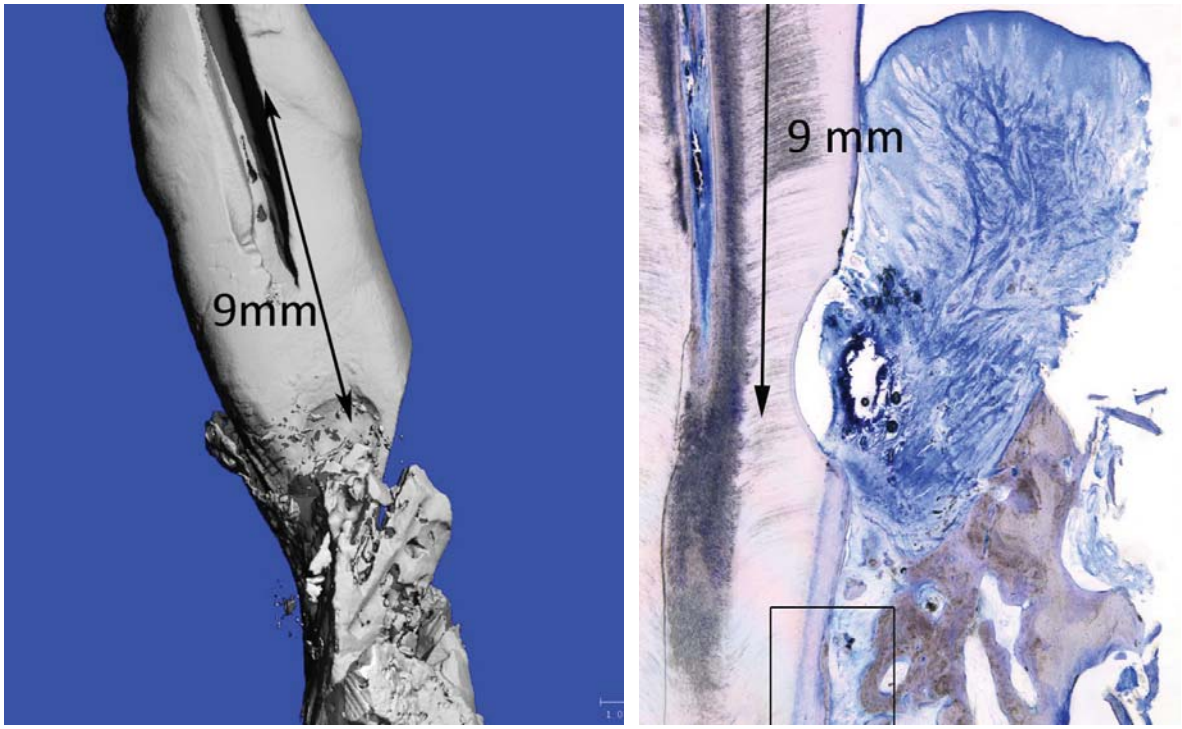

PATIENT 2, TOOTH 25 - LONG JUNCTIONAL EPITHELIUM

Mandibular right central incisor. The result coronal to the notch is LJE. There is evidence of new cementum adjacent to new bone that is functionally connected via new periodontal ligament, but on an assumed disease-free root surface below the experimentally placed notch. The INSET at the bottom of the image is enlarged on the next page.

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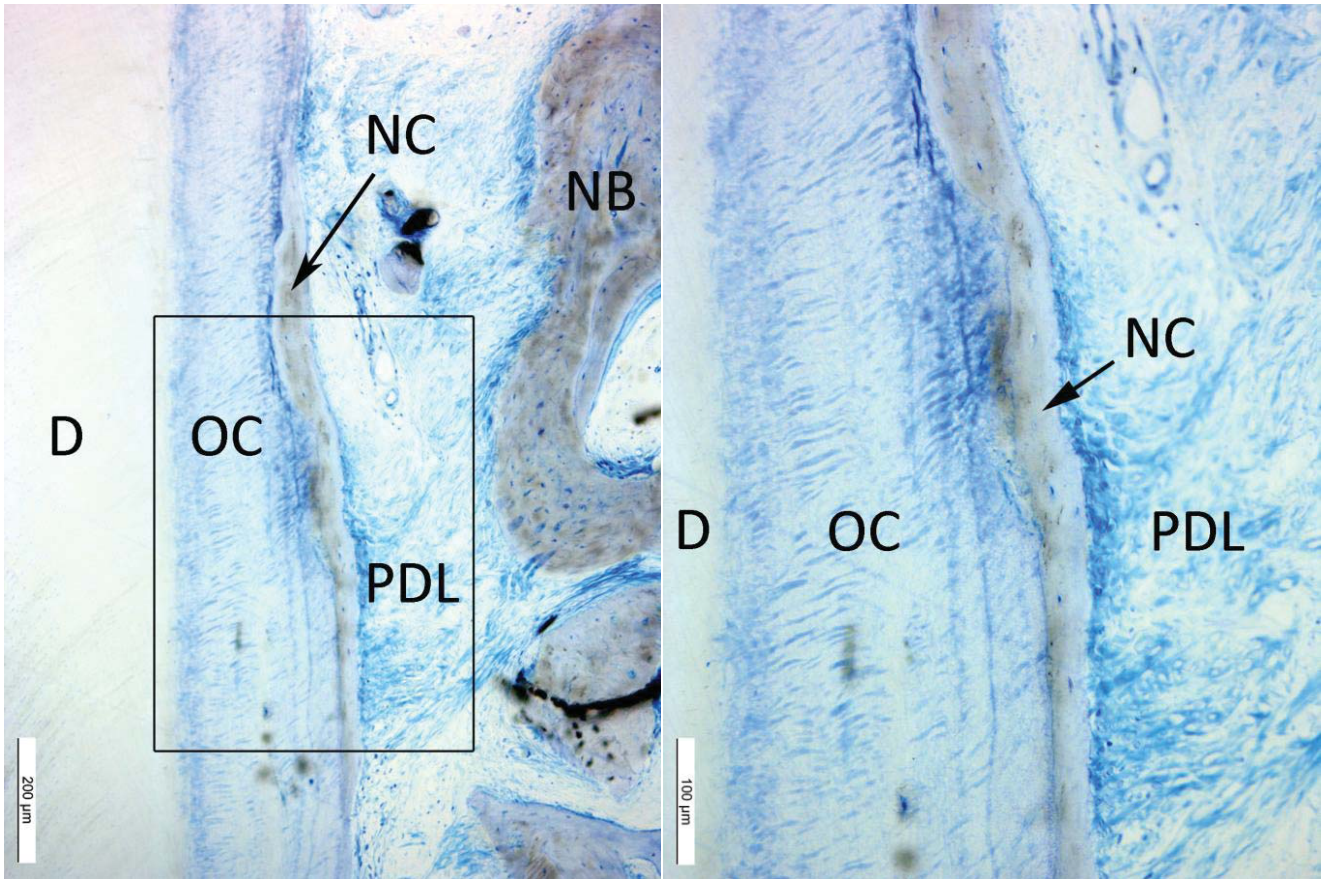

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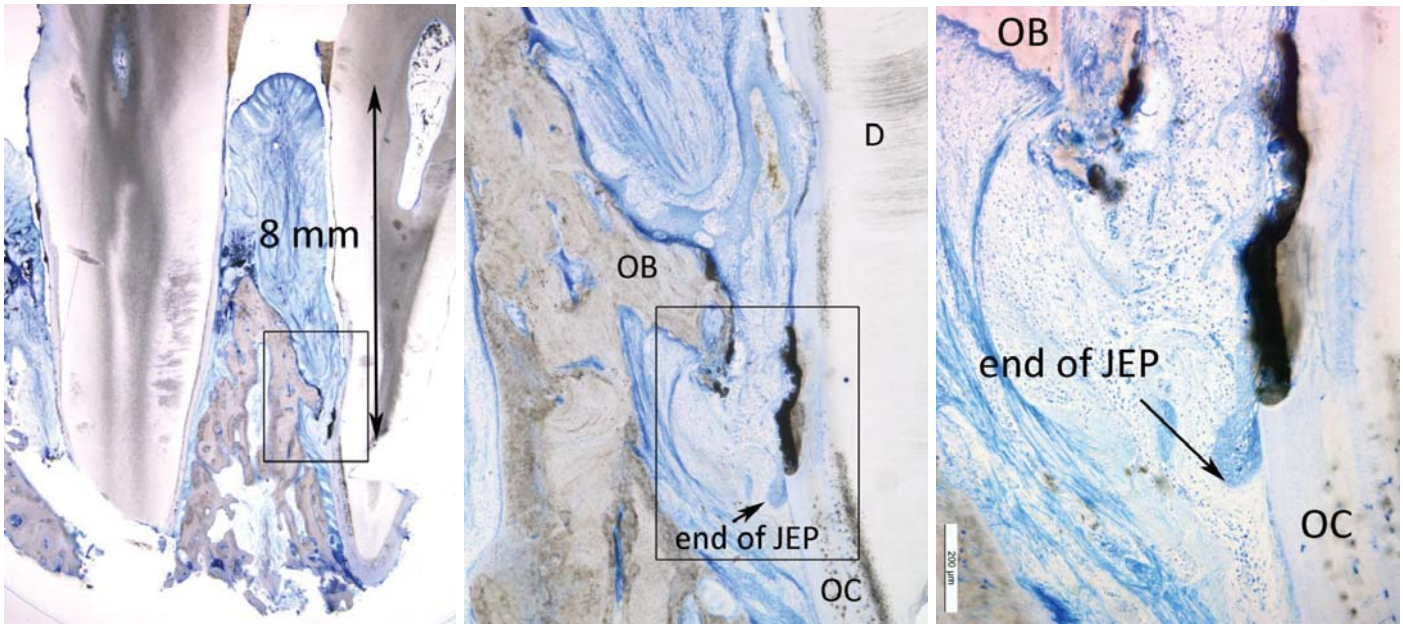

PATIENT 3, TOOTH 22 (L) and TOOTH 21 (R) - LONG JUNCTIONAL EPITHELIUM

Healing was observed via long junctional epithelium extending to the level of the calculus notch with no new cementum or new bone. Four out of ten specimens healed via LJE.

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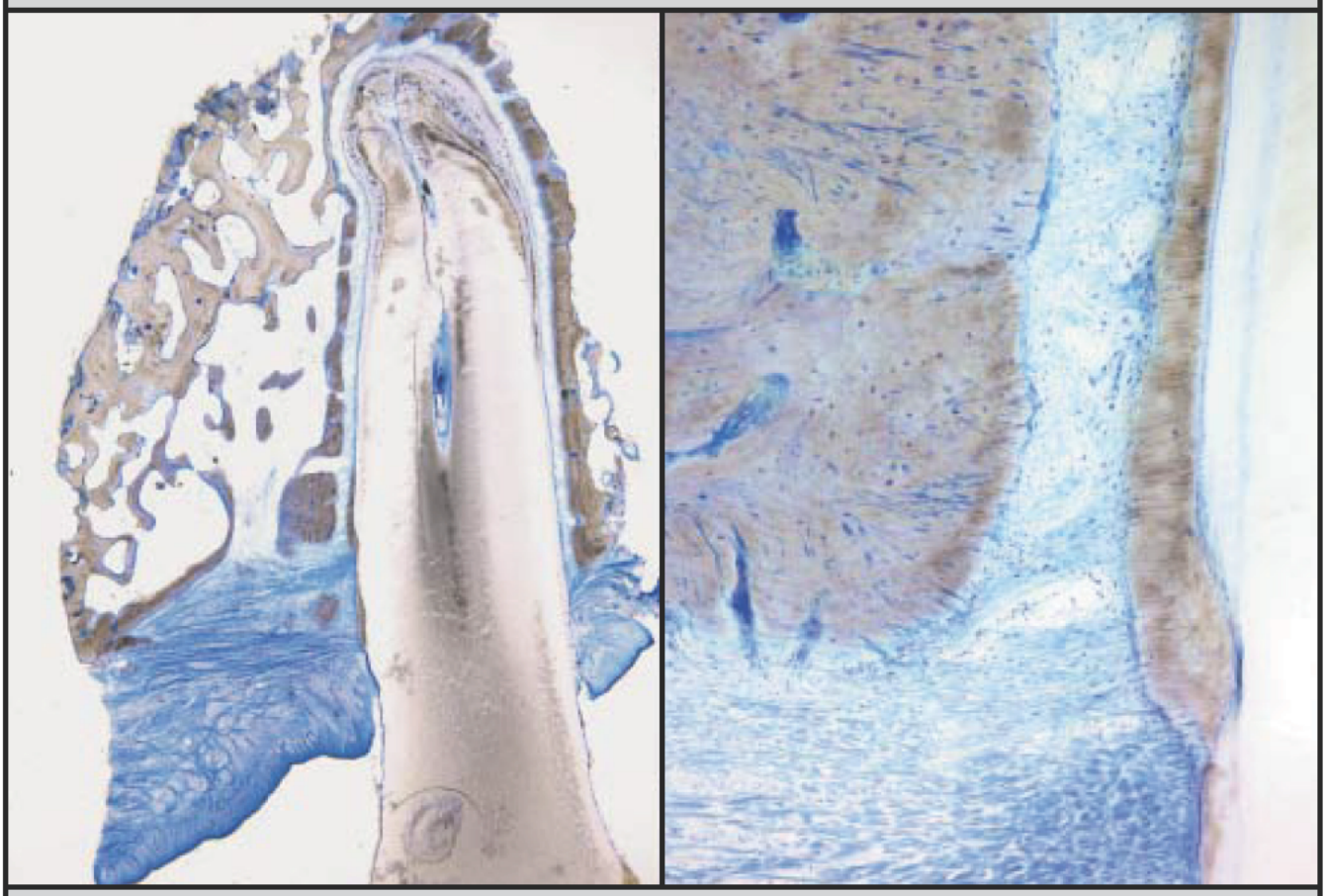

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Human Clinical and Histologic Evaluation of Laser-Assisted New Attachment Procedure

Marc L. Nevins, DMD, MMSc[1]/Marcelo Camelo, DDS[2]
Peter Schupbach, PhD[3]/Soo-Woo Kim, DMD, MS[4]
David M. Kim, DDS, DMSc[5]/Myron Nevins, DDS[6]

This investigation was designed to evaluate the healing response to the laser-assisted new attachment procedure (LANAP). Eight patients presenting with 12 teeth predetermined to be surgically extracted were enrolled and consented to treatment with full-mouth LANAP therapy. LANAP surgical therapy consisted of a first pass with a 360-µm fiber diameter, laser settings with verified output of 4.0 W and energy density of 1,965 mJ/mm², 100-µs pulse duration, and 20 Hz applied from the gingival margin to the base of the pocket parallel to the root surface and moved laterally and apically to remove the diseased pocket epithelium. The teeth were aggressively scaled and root planed with piezo ultrasonic instrumentation. A second pass was performed with a 360-µm fiber diameter, laser settings with verified output of 4.0 W and energy density of 1,965 mJ/mm², 650-µs pulse duration, and 20 Hz applied from the apical extent of the bone defect to the gingival margin. After 9 months of healing, en bloc biopsy extractions were provided. Ten teeth were analyzed histologically to assess the periodontal wound healing. Five teeth evidenced a degree of periodontal regeneration with new cementum, periodontal ligament, and alveolar bone. One tooth had new attachment with new cementum and inserting collagen fibers, and four teeth healed via a long junctional epithelium. LANAP therapy should be further investigated with long-term clinical trials to compare the stability of clinical results to conventional therapy. This report provides evidence that LANAP therapy can induce periodontal regeneration. (Int J Periodontics Restorative Dent 2012;32:497–507.)

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Laser therapy remains controversial in the field of periodontics.[1–3] Lasers of varying wavelengths (635 to 10,600 nm) used for nonsurgical and surgical periodontal and peri-implant therapy include neodymium:yttrium-aluminum-garnet (Nd:YAG), carbon dioxide, diode, and erbium:yttrium-aluminum-garnet (Er:YAG).[4–7] It is important to note that lasers of varying wavelengths have different levels of tissue penetration depending on reflection, scatter, and absorption.[8] Therefore, each therapy must be individually investigated with a specific laser. Each laser cannot be expected to replicate results of a laser of a different wavelength even when used to perform a similar therapy. Periodontal therapy utilizing a laser has been reported as a monotherapy,[9] as an adjunct to scaling and root planing,[5] for root debridement combined with surgical or nonsurgical therapy,[9,10] and to perform surgical laser-assisted new attachment procedures (LANAP).[11,12]

The primary goal of periodontal therapy is to establish periodontal health with pocket reduction and attachment gain, preferably

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through periodontal regeneration.[13] Periodontal regeneration is defined as establishing a new attachment apparatus on a previously diseased root surface via new cementum, new periodontal ligament (PDL), and new bone.[13] Multiple regenerative therapies have demonstrated adequate documentation of new periodontal structures regenerated adjacent to a calculus notch to meet these criteria.[13–19] These therapies all utilize surgical placement of a bone replacement graft material (autogenous, allogenic, or xenogenic) or a biologic agent (growth factor or amelogenins) with or without the combination of a barrier membrane. Most of these reports include the use of periodontal surgical flap procedures. Mellonig et al[20] reported the ability to stimulate periodontal regeneration when combining scaling and root planing with enamel matrix derivative application as a nonsurgical/flapless therapy.

There is desire among clinicians and patients to identify less invasive therapeutic options that can provide periodontal regeneration. Given the variations in clinical predictability of current therapies, it is unusual to provide full-mouth therapy via regenerative techniques even though patients may present with periodontal disease throughout their dentition. There is an undertreatment of periodontal disease based on patient and clinician perceptions regarding negative side effects of periodontal flap surgery such as pain, recession, dentinal sensitivity, and postoperative discomfort.[12] Minimally invasive laser periodontal therapy utilizing the patented LANAP protocol has been advocated for periodontal treatment but has limited clinical research demonstrating its efficacy and predictability. There is little known about the biology of the wound-healing process for these procedures.

The purpose of this study was to histologically evaluate the healing response to minimally invasive laser-assisted periodontal surgical therapy (LANAP).

Method and materials

This investigation was designed and implemented as a single-center, prospective clinical study with enrollment completed from May 1 through June 30, 2010. Subjects provided informed consent according to the Declaration of Helsinki of 1975, as revised in 2000. A total of 12 periodontal defects were identified in 8 subjects with advanced periodontitis. Eligibility required subjects to be between the ages of 18 and 70 years and have at least 1 tooth diagnosed and prescribed for extraction with a probing depth ≥ 7 mm and radiographic suggestion of a 4-mm or deeper intrabony defect. Subjects were excluded from the study if they had congenital or metabolic bone disorders, immunosuppressive therapy, or disease that may affect wound healing; were current smokers (within 6 months of entry into the study); or were pregnant or planning pregnancy during the course of the study. In addition, subjects with a history of active periodontal surgical treatment or scaling and root planing during the past 12 months were excluded.

At the screening visit, eligibility was assessed, patient histories were taken, and extra- and intraoral examinations were performed. The study teeth and primary study sites were identified prior to beginning the surgical visit, and baseline clinical measurements were recorded. Full-mouth LANAP therapy was provided in a single visit one arch at a time.

Clinical measurement and notch validation

Prior to enrolling patients, the periodontal examiner participated in a calibration training session. Probing and recession depth were measured and attachment levels calculated. Levels of intra- and interexaminer reliability were found to be within prespecified limits, with greater than 90% repeatability.

A notch validation study was performed prior to initiating study procedures. Six teeth requiring extraction from patients not enrolled in the LANAP protocol were included after consent was obtained for participation. Prior to extraction, the level of calculus was identified with tactile sensation using a periodontal probe and no. 23 dental explorer. The site was then notched with a no. 1/2 round bur utilizing high-speed instrumentation at its

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apical extent that could be accessed with a dental handpiece. No flap was raised. The notch was placed on the root surface with a horizontal groove into the cementum through the calculus. The teeth were extracted, photographed, and placed in formalin. Evidence of calculus apical to the notch was then confirmed via light microscopy and scanning electron microscopy. The calculus extended below the notch with a mean of 2.23 ± 1.28 mm, demonstrating a diseased root surface apical to the level of clinically detected and notched calculus.

Surgical procedure

The minimally invasive laser periodontal surgical therapy was provided using an Nd:YAG laser (PerioLase MVP-7, Millennium Dental Technologies). The surgical procedure was as follows: Clinical measurements for probing depth, recession depth, mobility, and furcation grade were accomplished for the study teeth according to the calibration protocol prior to administering local anesthesia. A notch was placed at the estimated apical extent of calculus on the study teeth using a no. 1/2 round bur with high-speed instrumentation to place a horizontal groove at the identified level on the root, and the location of the notch was measured relative to the cementoenamel junction for future reference. The laser was first used at a setting of 4.0 W, 100-μs pulse duration, and 20 Hz. It was passed from the gingival margin to the base of the pocket parallel to the root surface and moved laterally and apically to remove the diseased pocket epithelium and decontaminate the pocket. This was accomplished for all surfaces of the pocket for teeth in a single arch. The teeth were aggressively scaled and root planed with piezo ultrasonic instrumentation. Four or five piezo tips (Piezon Master 400, EMS and Piezosurgery, Mectron) were used on each root surface with repetitive cleaning until the roots were smooth and there was no visual or tactile evidence of remaining calculus. This can result in reduction of the depth of the previously placed notch, necessitating another measurement to confirm the notch location. The root preparation was performed from the coronal aspect of the teeth to the base of the intrabony defect, including the notched root surface. Once root preparation was complete, the circumferences of the teeth were passed with hand instrumentation to the level of the PDL either with a Piezo tip insert (EMS) or with a no. 11 periodontal knife. An attempt was made to bluntly dissect any remaining fibers and to press the instrument into the PDL space to stimulate vascular access to the periodontal wound. A second pass with the laser at a setting of 4.0 W, 650-μs pulse duration, and 20 Hz was performed from the apical extent of the defect to the gingival margin. The surgical sequence was repeated for the other arch.

Occlusal adjustment with selective grinding and extra- or intra-

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coronal splinting of the teeth was provided immediately postoperatively and as needed at follow-up visits to eliminate mobility. Patients were given the following postoperative instructions and medications: 0.12% chlorhexidine mouthrinse bid for 4 weeks, oral antibiotics (amoxicillin 500 mg) every 8 hours for 7 days, and anti-inflammatory analgesics for pain relief as needed (ibuprofen 600 mg, every 6 hours). Tooth-brushing was modified to protect against dislodging the fibrin clot. Patients were instructed to only brush the coronal tooth surfaces for the first 2 weeks postoperatively.

Patients were seen for follow-up care and oral hygiene instructions at 7, 14, 28, 42, and 56 days. The surgical sites were inspected and gently cleaned with chlorhexidine-soaked gauze, and teeth were gently cleaned supragingivally. Prophylaxis was provided, and hygiene was reviewed with the patient at 2.5, 4, 5.5, 7, and 8.5 months. Radiographs were updated at 5.5 and 9 months.

At 9 months, en bloc biopsy of the study teeth was performed. Prior to providing local anesthesia, full-mouth clinical measurements were performed, including probing depth, recession depth, mobility, and furcation grade. Guiding grooves for histologic preparation were placed on the coronal tooth structure over the study site. Each study tooth and a measured amount of surrounding tissue and bone were removed en bloc as described previously.[17] Biopsy sites were reconstructed with regenerative procedures in preparation for implant placement and subsequent prosthetic reconstruction with implant-supported prostheses. Biopsy specimens were stored in 10% formalin.

Microcomputed tomography

Specimens were scanned using a high-resolution microcomputed tomography (micro-CT) system (μCT 40, Scanco Medical) in multislice mode. Each image dataset consisted of approximately 600 micro-CT slice images. The specimens were scanned in high-resolution mode with an x-, y-, and z-resolution of 16 μm. The image datasets were used to produce three-dimensional views of the specimens using special software (Scanco Medical).

Light microscopy

Fixed samples were prepared for the preparation of nondemineralized ground sections according to the technique of Donath and Breuner.[21] The core specimens were processed by dehydration in a graded series of alcohols over a period of at least 9 days at standard temperature and pressure while constantly shaking. Then, the specimens were infiltrated with a graded series of alcohols and Technovit 7200 VLC embedding resin (Heraeus Kulzer) over a period of at least 12 days at standard temperature and pressure while constantly shaking. When finished, specimens were placed in three consecutive containers of 100% Technovit 7200 VLC for 24 hours each at standard temperature and pressure while constantly shaking.

Following dehydration and infiltration, specimens were embedded in Technovit 7200 VLC and polymerized using 450 nm of light for 10 hours, never exceeding 40°C.

Polymerized blocks were sliced longitudinally along the orientation grooves of the teeth, applied by the surgeon using an Exakt cutting unit (Exakt). This involved preparing a section of approximately 150 μm using the cutting/grinding instrument and then finishing the section to 30 to 50 μm using the microgrinding unit. A final polish was used with 0.1-μm diamond polishing paste.

The sections were stained with Sanderson RBS (methylene blue and potassium permanganate stain). Sections were enclosed by cover slips for analysis by means of both brightfield and polarized light microscopic evaluation.

Backscatter scanning electron microscopy

Specimens were glued to aluminum holders for backscatter scanning electron microscopy evaluation. The surface to be examined was highly polished with diamond pastes and thoroughly cleaned in an ultrasonic cleaner. Thereafter, the polished surface was sputter-coated with a 6-nm-thick carbon layer using an SCD-500 sputter coater (Bal-Tec). The specimen was examined using

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Table 1 Clinical results (mm) for study teeth at baseline and 9 months

Patient	Tooth no.*	Baseline			9 mo			PD reduction	CAL gain
		PD	Recession	CAL	PD	Recession	CAL		
1	34	9	0	9	3	4	7	6	2
2	41	8	2	10	3	5	8	5	2
2	45	14	2	16	4	5	9	10	7
3	34	10	0	11	7	4	8	3	3
3	33	10	0	10	5	2	7	5	3
4	15	10	2	12	8	2	10	2	2
5	36	16	0	16	6	1	7	10	9
5	33	12	0	12	4	3	7	8	5
5	45	9	0	9	6	1	7	3	2
6	26	9	2	11	4	2	6	5	5
7	46	8	0	8	4	3	7	4	1
8	27	10	0	10	6	0	6	4	4
Mean		10.4	0.7	11.2	5.0	2.7	7.4	5.4	3.8
Standard deviation		2.43	0.98	2.55	1.60	1.61	1.16	2.64	2.38

PD = probing depth; CAL = clinical attachment level.
*FDI tooth-numbering system.

a Zeiss VPN-40 field cathode scanning electron microscope using the backscatter detector.

Results

Eight patients with 12 teeth identified for extraction and histologic analysis were enrolled in the study. All sites healed uneventfully with no unexpected adverse events related to the LANAP surgical treatment. The mean total energy used per patient was 6,034 J, with a mean 3,344 J for the mandible and 2,691 J for the maxilla. Some patients experienced increased dentinal sensitivity during the first 4 weeks postoperatively, which then decreased to within normal limits. There were no signs of root damage from the laser therapy noted clinically or histologically. The 12 study teeth presented with a mean initial clinical attachment level (CAL) of 11.2 ± 2.50 mm, probing depth (PD) of 10.4 ± 2.43 mm, and recession of 0.7 ± 0.98 mm. After 9 months, these sites had a mean CAL gain of 3.8 ± 2.38 mm and PD reduction of 5.4 ± 2.64 mm. This resulted in a postoperative mean CAL of 7.4 ± 1.16 mm, PD of 5.0 ± 1.60 mm, and recession of 2.7 ± 1.61 mm (Table 1).

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Table 2 Histologic analysis of study teeth

Patient (tooth no.*)	Healing mechanism
1 (34)	Regeneration
2 (41) 2 (45)	LJE New attachment
3 (34) 3 (33)	LJE LJE
4 (15)	LJE
5 (36) 5 (33)	Regeneration Regeneration
6 (26)	Regeneration
8 (27)	Regeneration

LJE = long junctional epithelium.
*FDI tooth-numbering system.

Twelve teeth were evaluated using micro-CT and then prepared for histologic evaluation. Two teeth splintered during histologic preparation and were not available for microscopic evaluation. Periodontal wound healing evaluation coronal to the calculus notch revealed that five teeth healed with periodontal regeneration, evidencing new cementum, new PDL, and new alveolar bone (Table 2). One tooth had a new attachment apparatus with new cementum and inserting collagen fibers, and four teeth healed via junctional epithelium.

Four teeth in three patients healed via long junctional epithelium, with one of these evidencing new cementum and reattachment apical to the calculus notch. Two teeth (patient 3, mandibular left canine and first premolar) that healed with a long junctional epithelium are presented as a case example. Neither the postoperative periapical radiograph nor the micro-CT scan evidenced any bone fill of the intrabony defects (Figs 1a to 1c). Histologic assessment revealed healing via long junctional epithelium to the level of the calculus notch (Figs 1d and 1e), with no new cementum or new bone.

Periodontal regeneration coronal to the calculus notch was confirmed for three teeth presenting with furcation involvement. One of these teeth presented with a grade III furcation (patient 6, maxillary left first molar), and two teeth were identified clinically as grade II

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Fig 1a *Pretreatment periapical radiograph demonstrating intrabony defects.*

Fig 1b *Posttreatment radiograph showing persistence of the defects.*

Fig 1c *Micro-CT scan confirming persistence of the defects.*

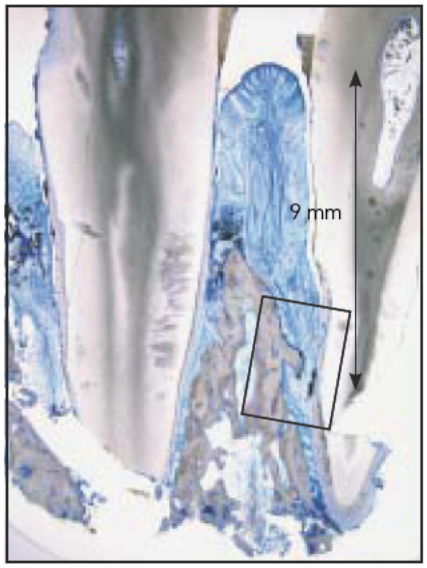
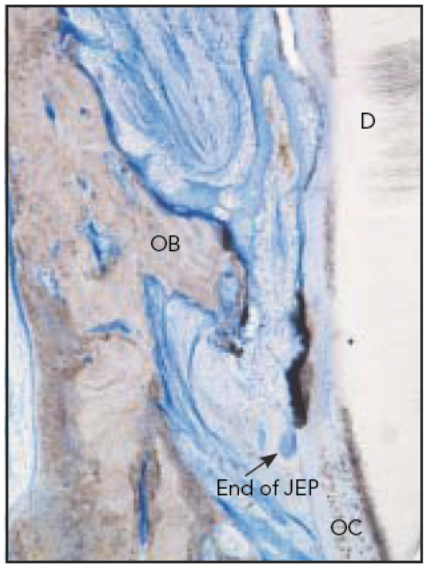


Fig 1d (left) *Panoramic histologic view used to assess the healing and the notch measurement to confirm the notch location. Healing was noted via long junctional epithelium.*

Fig 1e (right) *Higher magnification reveals the long junctional epithelium extending to the level of the calculus notch. OB = old bone; D = dentin; JEP = junctional epithelium; OC = old cementum.*



furcations (patient 3, mandibular left first molar and patient 8, maxillary left second molar) but surgically identified as grade III furcations. Although none of the furcations closed or were reduced in grade, they demonstrated significant CAL gain and histologic assessment of regeneration.

The mandibular left first premolar in patient 1 presented with a 9-mm CAL and 9-mm PD at baseline. After 9 months, there was a 2-mm CAL gain with a 4-mm recession and residual probing depth of 3 mm. The micro-CT scan easily identified the level of the calculus notch and was used in establishing

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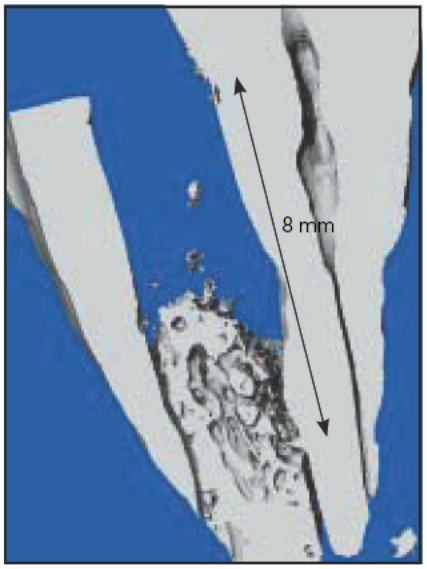
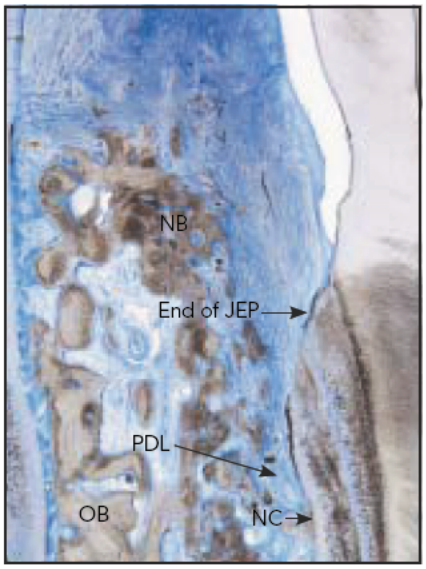


Fig 2a (left) *Micro-CT scan with 8-mm notch measurement from the cemento-enamel junction. There appeared to be significant bone fill of the defect proximal to the root surface.*

Fig 2b (right) *Histology was consistent with the micro-CT scan. New cementum* (NC), *periodontal ligament* (PDL), *and new bone* (NB) *were evident, demonstrating periodontal regeneration. The epithelium was limited coronal to the regeneration* (end of JEP). *Note the cervical notching of the root surface from the extensive root planing to remove the heavy calculus deposits. OB = old bone; JEP = junctional epithelium.*



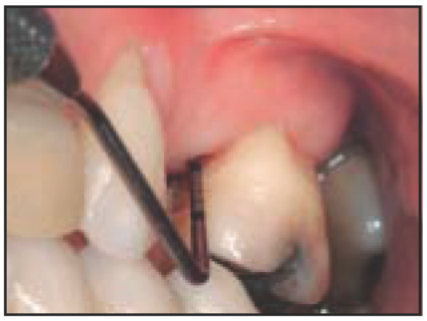


Fig 3a *Maxillary left first molar presenting with an initial CAL of 11 mm, PD of 9 mm, and grade III furcation.*

Fig 3b *Preoperative radiograph demonstrating a deep intrabony defect on the mesial surface and suggesting furcation invasion.*

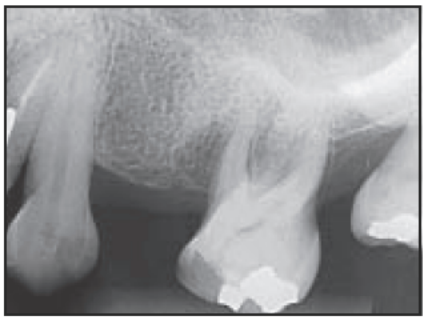


Fig 3c *Postoperative radiograph suggestive of bone fill and improved prognosis.*

the histologic landmarks (Figs 2a and 2b). There was an outgrowth of new cementum at the level of the calculus notch, which extended coronally with the adjacent PDL and new alveolar bone (Fig 2b).

A maxillary left first molar (patient 6) presented with a deep intrabony defect on the mesial surface with a baseline CAL of 11 mm and PD of 9 mm (Figs 3a and 3b). The postoperative radiograph showed bone fill (Fig 3c) and a 5-mm CAL gain with no recession (postoperative measurements: CAL, 6 mm; PD, 4 mm). Histologic evaluation revealed new bone proximal to the mesial root surface (Fig 3d). The higher-magnification view revealed a thick layer of new cementum on the root surface extending several millimeters coronal to the calculus notch with inserting Sharpey fibers crossing the PDL to the adjacent

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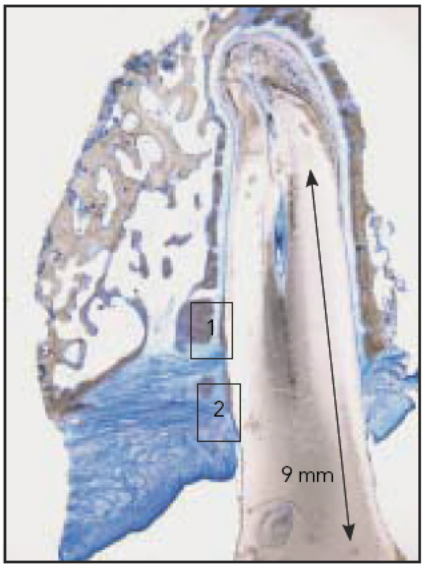

Fig 3d *Panoramic view showing bone fill of the intrabony defect and periodontal regeneration. The 9-mm notch measurement from the cementoenamel junction confirms the notch location.*

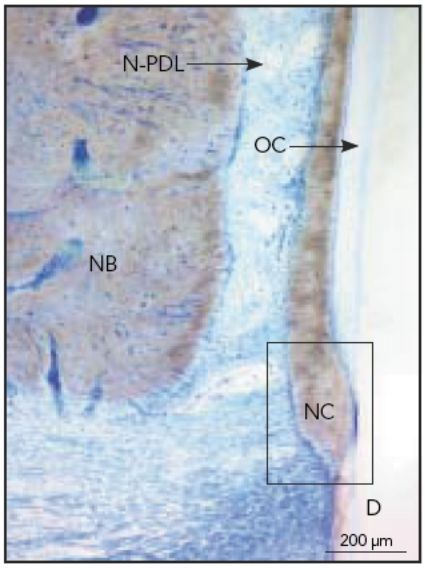

Fig 3e *Higher-magnification view of box 1 in Fig 3d revealed a layer of new cementum* (NC) *extending to the coronal extent of the defect with adjacent periodontal ligament* (N-PDL) *and new bone* (NB) *defining periodontal regeneration. OC = old cementum; D = dentin.*

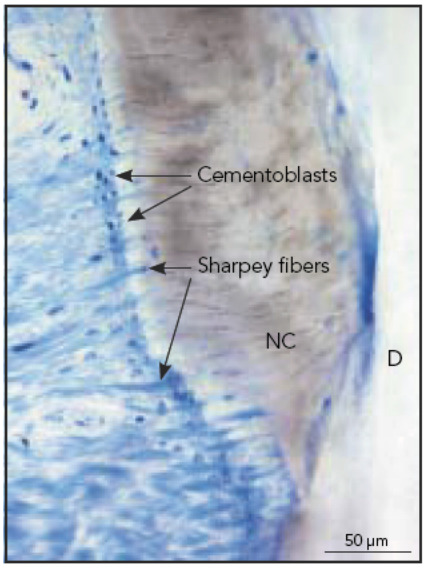

Fig 3f *Inserting Sharpey fibers into the new cementum and presence of cementoblasts (magnified view of box in Fig 3e). NC = new cementum; D = dentin.*

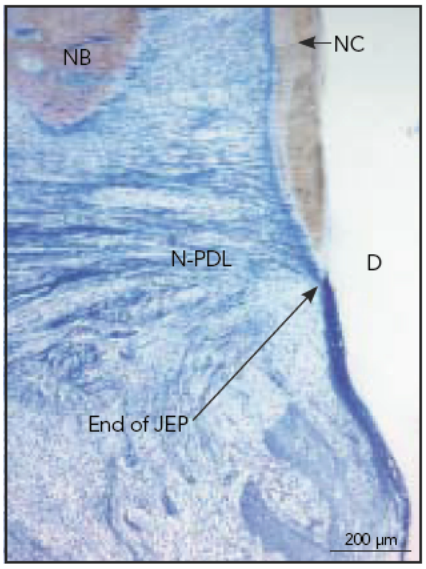

Fig 3g (left) *The supracrestal environment regenerated to its natural state with supracrestal inserting collagen fibers into the new cementum* (NC) *just apical to the junctional epithelium* (JEP) *(higher-magnification view of box 2 in Fig 3d). NB = new bone; N-PDL = new periodontal ligament; D = dentin.*

Fig 3h (right) *Backscatter electron microscopy confirmed the histologic assessment. The layers of root surface with dentin* (D), *old cementum, and new cementum* (NC) *could be well visualized. NB = new bone.*

alveolar bone (Fig 3e). Cementoblasts were visible on the surface of the cementum (Figs 3f and 3g). Backscatter electron microscopy confirmed the findings from the light microscopic examination and helped to visualize the layers of root structure, including dentin, old cementum, and new cementum (Fig 3h).

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Discussion

This report presents evidence that using LANAP therapy for microinvasive periodontal therapy may result in periodontal regeneration adjacent to a calculus notch placed on the previously diseased root surface. Six of 10 teeth evaluated demonstrated a regenerative response, with 5 undergoing periodontal regeneration and 1 receiving new attachment. The ability to improve the periodontal condition even for sites with furcation involvement was evident, with 3 teeth with grade III furcation involvement demonstrating some degree of periodontal regeneration.

The only previous histologic report on the LANAP protocol was that published by Yukna et al,[22] in which six LANAP-treated teeth demonstrated evidence of new attachment with new cementum and inserting collagen fibers. Teeth treated with scaling and root planing healed via long junctional epithelium, with one site evidencing minimal new cemetum. There are differences in the treatment protocols that should be highlighted, including that this report allowed 9 months of healing versus only 3 months for the study by Yukna et al.[22] The current study utilized full-mouth LANAP treatment, whereas the previous study utilized a split-mouth design, treating the specific study teeth either with laser surgery or scaling and root planing, and limited the root preparation coronal to the calculus notch. This study provided root preparation with intensive root planing with piezo ultrasonic instrumentation from the coronal aspect of the teeth down to the level of the PDL. Of interest is that the previous histologic study demonstrated new cementum and new attachment even though there was no root preparation below the notch where there may have been additional toxins or calculus. Previous publications have demonstrated evidence of human histology for regeneration with new cementum over old cementum, dentin, calculus, and an enamel projection.[14,19]

Validation for notch placement was necessary because the previously accepted definition for notch placement is that of a visual procedure. The validation confirmed that tactile sensation can be used to place the notch in calculus with a no. 1/2 round bur and high-speed instrumentation in a flapless environment preoperatively. The use of a notch measurement and the micro-CT scan were helpful to confirm the location of the notch for histologic assessment.

LANAP appears to be a safe procedure that resulted in apparent periodontal regeneration. There were no significant side effects beyond dentinal hypersensitivity or gingival recession and no damage to the root surfaces.[23] Without histology, it would not be possible to evaluate the biologic potential of the surgical procedure, and this information is essential to combine clinical and radiographic assessment and the healing potential for patient care.

Recent clinical innovations and research have focused on minimally invasive surgical therapies.[24–27] For example, Cortellini and Tonetti demonstrated improved wound stability using a modified minimally invasive surgical technique (M-MIST) that increased the likelihood of blood clot stabilization as a principle of periodontal wound healing for regeneration.[28] This research was further supported by a prospective study comparing M-MIST with and without application of enamel matrix derivative.[29] The outcomes were similar for both groups, with CAL gains of 4.1 ± 1.4 mm for the M-MIST control group and 4.1 ± 1.2 mm for the EMD/M-MIST group. The improved wound stability appears to be directly related to the periodontal wound-healing results. This is similar with the LANAP procedure, which utilizes a microinvasive approach. After the first laser pass, the tissues are relaxed and can be gently reflected to visualize the root surface with the use of limited magnification (4.5× for this study). The second pass with the laser stimulates the blood clot, which is the foundation for periodontal wound healing.

Conclusions

This study provides further evidence that periodontal regeneration may take place following treatment via LANAP. It should be noted that an apical calculus notch may not have been placed in the exact manner as required by the definition for periodontal regeneration.

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K151763/S1

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February 12, 2016

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Re: K151763 Additional Information Requested August 27, 2015
Deficiency List Response
510(K) Submission – Traditional 510(k)
Millennium Dental Technologies, Inc.
Establishment Registration Number: 2031763

The enclosed additional information (K151763 Deficiency List Response) is submitted on behalf of Millennium Dental Technologies, Inc., Establishment Registration Number 2031763. It is to be logged in as a supplement to the K151763 submission.

The eCopy is an exact duplicate of the paper copy.

This response consists of this cover letter and seven separate attachments:

- Attachment 1: K151763 Deficiency List Response (2 pages) that addresses FDA's deficiency list received August 27, 2015.
- Attachment 2: Completed FDA Form 3881 Indication for Use statement (2 pages). This form is a duplicate of Document 007 Indications for Use Form 3881 that was included in the June 22, 2015 510(K) paper submission.
- Attachment 3: Updated Table of Contents, Table of Figures, and Section 7 Sterilization (9 pages total) of the PerioLase® MVP-7™ Operator's Manual. These pages are intended to replace the corresponding pages in Appendix A of the June 22, 2015 510(K) paper submission.
- Attachment 4: Updated Software description (1 page). This page is intended to replace page 16-1 of the June 22, 2015 510(K) paper submission.
- Attachment 5: Updated 2011 Software Requirements Specification for a new controller board (11 pages). These pages are intended to be added to Appendix D2 of the June 22, 2015 510(K) paper submission.
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David M. Harris, PhD, is the official correspondent for Millennium Dental Technologies, Inc. for this submission. Please direct any questions or correspondence about this submission to our attention at the telephone number or address indicated.

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Enclosure: CD with electronic version of this application. *[MDT FDA 2015-2]*
cc: Executive Committee, Millennium Dental Technologies, Inc.

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MILLENNIUM DENTAL TECHNOLOGIES, INC.

K151763 510(k) Application

Additional Information Requested August 27, 2015

Deficiency List Response

PerioLase Nd:YAG Pulsed Dental Laser System

for

New Clinical Outcome Claim in Dentistry

February 12, 2016

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7. Sterilization

PerioLase® MVP-7™ – The beam delivery system may be sterilized using steam as described in section 7.2, below. Other methods of sterilization of the delivery system components are available, for example, ethylene oxide sterilization. For more information, please consult Customer Service at Millennium Dental Technologies, Inc., using the contact information on the cover of the Operator's Manual.

Cleaning and sterilization instructions are valid only when used with U.S. Food and Drug Administration (FDA)-cleared disinfectants and devices. Initial cleaning steps (7.1) should be done in a dedicated cleaning area promptly after use to prevent material from drying on the instrument and to prevent the spread of contamination. Sterilization parameters are valid only for instruments that are adequately cleaned.

The following accessories are required for proper cleaning and sterilization:

- Protective cap for the laser output (fiberport)
- Protective cap for the FiberFlex™ fiber
- Cannula brush (Item #190)
- Hospital-grade enzymatic detergent solution
- Lint-free, single-use cloths
- Ultrasonic cleaner
- Sterilization packaging
- Steam sterilizer

Sterilization parameters are valid only for properly installed, maintained, calibrated, and compliant reprocessing equipment in accordance with **ISO 17665-1:2006** and **ISO 11135:2014**.

Patients identified as at-risk for Creutzfeldt-Jakob disease (CJD) and related infections should be treated with single-use instruments only. Dispose instruments used or suspected of use on a patient with CJD after surgery and/or follow current national recommendations.

For additional information regarding cleaning and sterilization, consult national regulations and professional organizations' clinical practice guidelines. For additional information about the infection control procedures for the PerioLase®, consult Millennium Dental Technologies, Inc. using the contact information on the cover of the Operator's Manual.

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7.1 Preparing the Beam Delivery System

7.1.A Loosen the adjustable collet on the TrueFlex® handpiece (see figure below) and remove the FiberFlex™ fiber completely from the TrueFlex® handpiece by sliding it out.

Figure 7: TrueFlex® Handpiece, Unassembled

7.1.B Wipe the FiberFlex™ fiber with a high-level disinfectant.

7.1.C Use the provided cleaving tool to cleave the tip of the FiberFlex™ fiber as described in section 3.3 of the Operator's Manual.

7.1.D Use the provided stripping tool to remove enough of the C-flex jacket material to expose approximately 3" (76 mm) of bare fiber. Areas where blood has been wicked up between the C-Flex jacket and the fiber must be cut off prior to sterilization. Always make sure there is enough jacket material to pass completely through the collet of the TrueFlex® handpiece. Otherwise, adjusting the length of the fiber beyond the cannula could cause the FiberFlex™ fiber to slip in the collet.

7.1.E Unscrew and separate the TrueFlex® handpiece body, collet, and stainless steel cannula.

7.1.E.i Ultrasonic Cleaning Procedure

Immerse and soak heavily soiled handpieces and cannulae in a hospital-grade enzymatic detergent solution for a minimum of ten minutes to loosen any dried soil or debris. Follow the detergent manufacturer's instructions for use for correct exposure time, temperature, water quality, and concentration.

Rinse all parts thoroughly for a minimum of two minutes under warm tap water. Manually clean the components as follows for a minimum of five minutes. Using room-temperature enzymatic detergent, scrub all external and internal surfaces with the cannula brush until all visible soil has been removed. It is important to make sure that the grooves and threads are effectively cleaned. Brush the inside of the cannula with the provided

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cannula brush (at least 5 back-and-forth repetitions). For best results place the handle end of the cannula brush into the cannula first and pull the brush end through the cannula rather than trying to push the brush headfirst through the cannula. It may be helpful to bend the cannula to less than 60° to clean it. Gently and firmly draw the cannula between a curved surface (such as the side of the TrueFlex® handpiece body) and the pad of your thumb to bend the cannula to the desired angle. Also, use the cannula brush to clean the inside of the TrueFlex® handpiece body with warm enzymatic detergent. Inspect for visible soil on exposed surfaces. Rinse thoroughly for a minimum of two minutes using warm tap water then place the fully disassembled parts inside a ziplock bag with some enzymatic detergent. Seal the bag and sonicate the parts in an ultrasonic cleaner for a minimum of 15 minutes. Rinse thoroughly with room-temperature tap water and prepare for sterilization.

Prior to packaging for sterilization, dry each component thoroughly inside and out to prevent corrosion and malfunction. Use a clean, soft, lint-free single-use cloth to prevent damage to the surface. Pay special attention to grooves or threads where fluid can accumulate. Dry hollow parts (handpiece and cannula) using an air jet with medical-grade compressed air.

Do not use any lubricating agents on the handpiece or cannula prior to or after sterilization.

7.1.F Use a soft brush or cloth to clean the cleaving tool with warm, clean, soapy water. Rinse and prepare for sterilization. Do not place the cleaving tool in an ultrasonic bath.

7.1.G The fiber stripping tool is to be cleaned / sterilized according to the manufacturer's instructions.

7.1.H Visually inspect the handpiece, cannula, and fiber for cleanliness using adequate lighting and magnification. If the components are determined not to be visually clean at the end of the cleaning procedure, repeat the relevant cleaning steps. Examine the cannula and discard if damaged. Inspect for evidence of damage or wear, discoloration, improper functioning. The cannula can be damaged and collapsed if folded at the brazed portion. The distal end of the cannula can be dented, "dinged," and damaged in such a way that the fiber is scratched or cleaved during use. Properly dispose of components determined to be unacceptable.

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7.2 Steam Sterilization Procedure

Use sterilization packaging that is designed to allow adequate sterilant penetration and maintenance of sterility. Ensure the sterilization packaging is labeled for sterilization parameters specified below.

The steam sterilization procedure should be performed in accordance with the directions of the manufacturer of the autoclave.

7.2.A Remove the FiberFlex™ fiber from the laser output (fiberport). Securely place the protective cap that came with the FiberFlex™ fiber onto the connector end to protect the connector from contamination. Place the protective cap that came with the PerioLase® on the laser output (fiberport).

Coil the FiberFlex™ fiber (not less than 6-inch (15.2-cm) coil diameter) and place the fiber into its own autoclave pouch for sterilization. Use a pouch at least 8" by 12" (20.3 by 30.4 cm). Seal the pouch.

7.2.B Place the disassembled TrueFlex® handpiece parts and cleaving tool into a separate small autoclave pouch or pouches. Seal the pouch or pouches.

7.2.C Sterilize by gravity-displacement steam autoclave for 15 minutes at a minimum of 132°C (270°F) with a minimum drying time of 15 minutes. Alternatively, sterilize by dynamic-air-removal steam autoclave for 4 minutes at a minimum of 132°C (270°F) with a minimum drying time of 20 minutes. Follow the prescribed minimum drying times after processing and before storage to eliminate moisture than can support the survival of contaminating microorganisms. Allow to cool before handling.

Note: The optical surfaces of the beam delivery FiberFlex™ fiber are very sensitive to contamination. The autoclave itself must be clean. If the same autoclave is used for sterilizing high- or low-speed air-turbine handpieces, the lubricating oils can contaminate the autoclave and be transferred to the optical surfaces of the FiberFlex™ fibers. This will seriously degrade the performance of the FiberFlex™ fibers and reduce their life. Clean the autoclave on a regular basis. **It is strongly recommended to clean the autoclave on a once-per-week schedule,** the normal cleaning schedule recommended by most major autoclave manufacturers. If any of the interior surfaces of the autoclave feel oily to the touch, it should be cleaned before sterilizing any optical FiberFlex™ fibers. Follow the manufacturer's instructions for cleaning.

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7.3 Reassembly of Components

Reassembly should be performed in the dedicated cleaning area. Follow the instructions for installation of the FiberFlex™ fiber in Section 2.3.K FiberFlex™ Fiber/TrueFlex® Handpiece Installation in Section 3.5 of the Operator's Manual. Verify the reassembly has been properly performed to assure that the PerioLase® is in operable condition for next use. Check the components for correct adjustment and function. Hold the FiberFlex™ fiber perpendicular to a flat, light-colored surface, place the laser in the READY mode, and ensure the red aiming beam emanates only from the end of the fiber tip.

Figure 8: TrueFlex® Handpiece, Assembled

7.4 Applicable Standards, Technical Information Reports, Recommended Practices, and Guidance Documents

Standards, Technical Information Reports, Recommended Practices, and Guidance Documents used in developing the cleaning and sterilization methods and validation procedures include:

Standards

- ANSI/AAMI ST77:2013: Containment devices for reusable medical device sterilization.
- ANSI/AAMI/ISO 11138-1:2006/(R) 2010: Sterilization of health care products – Biological Indicators – Part 1: General requirements.
- ANSI/AAMI/ISO 11138-3:2006/(R) 2010: Sterilization of healthcare products – Biological indicators – Part 3: Biological indicators for moist heat sterilization processes.
- ANSI/AAMI/ISO 11737-2:2009: Sterilization of medical devices – Microbiological methods – Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process.
- ANSI/AAMI/ISO 17665-1:2006: Sterilization of health care products – Moist heat – Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices.
- ISO 14161:2009: Sterilization of health care products – Biological indicators – Guidance for the selection, use and interpretation of results.

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ISO 17664:2004: Sterilization of medical devices – Information to be provided by the manufacturer for the processing of resterilizable medical devices

Technical Information Reports

AAMI TIR 12:2010: Designing, testing and labeling reusable medical devices for reprocessing in health care facilities: A guide for medical device manufacturers.

AAMI TIR 30:2011: A compendium of processes, materials, test methods, and acceptance criteria for cleaning reusable medical devices.

ANSI/AAMI/ISO TIR 17665-2:2009: Sterilization of health care products – Moist heat – Part 2: Guidance on the application of ANSI/AAMI/ISO 17665-1.

Recommended Practices

ANSI/AAMI ST79:2010: Comprehensive guide to steam sterilization and sterility assurance in health care facilities.

Guidance Documents

Premarket Notification [510(K)] Submission for medical sterilization packaging systems in health care facilities; Draft guidance for industry and FDA. Office of Device Evaluation, draft released for comment on March 7, 2002.

Reprocessing medical devices in health care settings: Validation methods and labeling – Guidance for industry and Food and Drug Administration staff. March 17, 2015.

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Software

The software for the PerioLase Nd:YAG Pulsed Dental Laser System was cleared under the previous PerioLase submissions, K010771, K014272, and K030290. Additionally, software changes were incorporated in 2011 to accommodate a new controller board that replaced the one that had become obsolete. The software has been validated to verify that there are no new safety and effectiveness issues.

During the design effort of the PerioLase Nd:YAG Pulsed Dental Laser System, all reasonable steps were taken to assure that hazards associated with the device were minimized. A Failure Modes and Effects Analysis (FMEA) of potential component failure conditions, effects, severity levels, and countermeasures was used to minimize the effects of failures.

Numerous documents were used as guidelines during the development of the FMEA analysis, including:

- EN 60601 Medical Laser Equipment
- EN 60825 Safety of Laser Products
- EN 61000 EMC.

Analysis of the software-related aspects of the FMEA analysis indicated a minor level of concern for the software, as failure of the system controller or touchscreen controller results in an inoperable system and laser emission is not allowed.

See Appendix D of this submission for documents related to FMEA and software requirements, design, and validation:

- Failure Modes and Effects Analysis (FMEA)
- Software Requirements Specification (SRS)
- Software Design Description (SDD)
- Software Validation Test Specification (SVTS).

Included in the documentation in either paragraph or tabular format are:

- an overview of the device features that are controlled by software and the intended operational environment (SRS);
- software description, programming language, and hardware platform (SDD);
- description of identified hardware and software hazards, including severity assessment, countermeasures and mitigations (FMEA);
- functional requirements (SRS);
- software design description (SDD);
- traceability matrix (SVTS);
- software validation procedures and results (SVTS);
- controller and display software version and date (SVTS).

Software validation testing (including initialization tests, standby mode tests, set up mode tests, service mode 1 and 2 tests, ready mode tests, firing mode tests, procedure screen tests, print screen tests, power screen display screen tests) was completed and all tested parameters passed (see SVTS documents). The software documentation supports all performance and safety claims.

Displays of information, prompts, and check and error codes are described in detail in the Operator's Manual (see Appendix A of this submission).

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MILLENNIUM DENTAL TECHNOLOGIES, INC.

Document Change Order

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(b)(4)Software Design Description

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(b)(4)Software Design Description

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