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Dear Kim,
Thank you for the additional information. We will incorporate this into our review.

Sincerely,
Stacie Gutowski, Ph.D.
Biomedical Engineer
ODE/DNPMD/NSDB
WO 66, Rm 2656
10903 New Hampshire Avenue
Silver Spring, MD 20993
(240) 402-6032
Stacie.Gutowski@fda.hhs.gov

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From: Kim Schmelzer [mailto (b)(6)
Sent: Monday, October 19, 2015 5:04 PM
To: Gutowski, Stacie
Subject: RE: K151790/S001 Follow-up Information Request

Staci,

I hope you had a good weekend!

(b)(4)

Let me know if you have any further questions or concerns.

Thank you,
Kim Schmelzer | Quality Manager
PMT Corporation | Permark
1500 Park Road Chanhassen MN 55317 USA

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

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Description: pmt_logo

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From: Gutowski, Stacie [mailto:Stacie.Gutowski@fda.hhs.gov]
Sent: Friday, October 16, 2015 7:56 AM
To: Kim Schmelzer
Cc: k151790@docs.fda.gov
Subject: RE: K151790/S001 Follow-up Information Request

Dear Ms. Schmelzer,
Thank you for following up with the requested information. (b)(4)

(b)(4)

Please let me know if you have any questions.
Stacie Gutowski, Ph.D.
Biomedical Engineer
ODE/DNPMD/NSDB
WO 66, Rm 2656
10903 New Hampshire Avenue
Silver Spring, MD 20993
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From: Kim Schmelzer [mailto: (b)(6)
Sent: Wednesday, October 14, 2015 2:15 PM
To: Gutowski, Stacie
Cc: k151790@docs.fda.gov
Subject: RE: K151790/S001 Follow-up Information Request

Stacie,

(b)(4)

Let me know if you have any questions or need clarification.

Thank you,
Kim Schmelzer | Quality Manager
PMT Corporation | Permark
1500 Park Road Chanhassen MN 55317 USA
D: +952.470.0866 | F: +952.470.0865
Toll Free: 1.800.MANKIND (626-5463)
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From: Gutowski, Stacie [mailto:Stacie.Gutowski@fda.hhs.gov]
Sent: Wednesday, October 14, 2015 11:38 AM
To: (b)(6)
Cc: k151790@docs.fda.gov
Subject: K151790/S001 Follow-up Information Request

Ms. Schmeizer,
We have completed administrative review of your submission (K151790) and have accepted the file for substantive review. (b)(4) (b)(4) Please see the attached RTA checklist for a description of the items needed for our review. Please email me with the updated documents, and be sure to cc the docs.fda.gov email address above on all future communications for this file. You only need to send the documentation for the items requested, no need to send the whole submission again.
Please let me know if you have any questions.

Stacie Gutowski, Ph.D.
Biomedical Engineer
ODE/DNPMD/NSDB
WO 66, Rm 2656
10903 New Hampshire Avenue
Silver Spring, MD 20993
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https://www.research.net/s/cdrhcustomerservice?O=400&D=460&B=462&E=&S=E

From: Stacie Gutowski [mailto:stacie.gutowski@fda.hhs.gov]
Sent: Wednesday, October 14, 2015 11:50 AM
To: (b)(6)
Cc: Gutowski, Stacie
Subject: K151790/S001 was Accepted

October 14, 2015

Acceptance Review Notification - Accepted

An administrative acceptance review was conducted on your premarket notification (510(k)) K151790/S001, and it was found to contain all of the necessary elements and information needed to proceed with the substantive review. We will contact you should we require any additional information during the course of the substantive review. The lead reviewer assigned to your submission is Stacie Gutowski.

*** This is a system-generated email notification ***

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Document type: TECHNICAL REPORT	Document No. (b)(4)	Page 1 of 14
Document title: (b)(4)	Effective Date 9/1/09	Current Rev. (b)(4)

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Sterile Label PN 11930-002 Platinum Depth Product Label

PMT® Corporation

CE 0120

DEPTHALON®

Depth Electrode

Electrode de profondeur, Tiefenelektrode
El Electrodo del profundidad, L'Elettrodo di profondità

REF 2102 -__ __ - __ __ __

Platinum (Platine), (Platin), (El platino), (Il platino)

LOT _____

_____
Year - Month

SINGLE USE ONLY

STERILE EO

LATEX
Not made with natural rubber latex

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(952) 470-0866
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Chessington, Surrey KT9 1RH
England
Telephone: 44 20 8391 4455

WARNING: Federal Law (USA) restricts this device to the sale on or by a physician

NOTE: DEVICE IS INTENDED FOR TEMPORARY USE (≤ 30 DAYS).
Note: Ce produit est recommende pour usage temporaire de moins de 30 jours
Nota: El aparato desinato para uso temporal (≤ 30 days)
Anmerkung: Das Produkt ist fur den Einsatz bis 30 Tag vorgesehen (≤ 30 days)
Note: Prodotto inteso solo per uso temporaneo (≤ 30 giorni)

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Non-Sterile Label PN 11930-002 Platinum Depth Product Label

PMT® Corporation

CE 0120

DEPTHALON®

Depth Electrode

Electrode de profondeur, Tiefenelektrode
El Electrodo del profundidad, L'Elettrodo di profondità

REF 2102 -__ __ - __ __ __

Platinum (Platine), (Platin), (El platino), (Il platino)

LOT _____

NON STERILE

SINGLE USE ONLY

LATEX

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Chanhassen, MN 55317-USA
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Sterile Label PN 11930-003 Platinum Microwire Depth Label

PMT® Corporation

CE 0120

DEPTHALON®

Microwire Depth Electrode

Electrode de profondeur, Tiefenelektrode
El Electrodo del profundidad, L'Elettrodo di profondità

REF **2104 -__ __ - __ __ __**

Platinum (Platine), (Platin), (El platino), (Il platino)

LOT _____

_____
Year - Month

SINGLE USE ONLY

STERILE EO

LATEX
Not made with natural rubber latex

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Chanhassen, MN 55317-USA
Telephone: (800) MANKIND
(952) 470-0866
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Non-Sterile Label PN 11931-003 Platinum Microwire Depth Label

PMT® Corporation

CE 0120

DEPTHALON®

Microwire Depth Electrode

Electrode de profondeur, Tiefenelektrode
El Electrodo del profundidad, L'Elettrodo di profondità

REF 2104 -__ __ - __ __ __

Platinum (Platine), (Platin), (El platino), (Il platino)

LOT _____

NON STERILE

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LATEX

Not made with natural rubber latex

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Anmerkung: Das Produkt ist fur den Einsatz bis 30 Tag vorgesehen (≤ 30 days)

Note: Prodotto inteso solo per uso temporaneo (≤ 30 giorni)

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Sterile Depthalon Electrode Box Label Model 2102 - Platinum

PMT® Corporation

CE 0120

DEPTHALON®

Depth Electrode

Electrode de profondeur, Tiefenelektrode
El Electrodo del profundidad, L'Elettrodo di profondità

REF 2102 -__ __ - __ __ __

Platinum (Platine), (Platin), (El platino), (Il platino)

LOT _____

_____
Year - Month

SINGLE USE ONLY

STERILE EO

Not made with natural rubber latex

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1500 Park Road
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Anmerkung: Das Produkt ist für den Einsatz bis 30 Tag vorgesehen (≤ 30 days)
Note: Prodotto inteso solo per uso temporaneo (≤ 30 giorni)

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PMT® **DEPTHALON® Depth Electrode** CE 0120

REF 2102 -__ __ - __ __ __
Platinum

LOT _____

_____
Year - Month

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

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Non-sterile Depthalon Electrode Box Label Model 2102 – Platinum

PMT® Corporation

CE 0120

DEPTHALON®

Depth Electrode

Electrode de profondeur, Tiefenelektrode
El Electrodo del profundidad, L'Elettrodo di profondità

REF **2102 -__ __ - __ __ __**

Platinum (Platine), (Platin), (El platino), (Il platino)

LOT _____

NON STERILE

SINGLE USE ONLY

LATEX
Not made with natural rubber latex

PMT Corporation
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Fax: (952) 470-0865

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Note: Prodotto inteso solo per uso temporaneo (≤ 30 giorni)

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PMT® **DEPTHALON® Depth Electrode** CE 0120

REF **2102 -__ __ - __ __ __**
Platinum

LOT _____

NON-STERILE
NON STERILE, NO ESTERIL, NICHT STERIL

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

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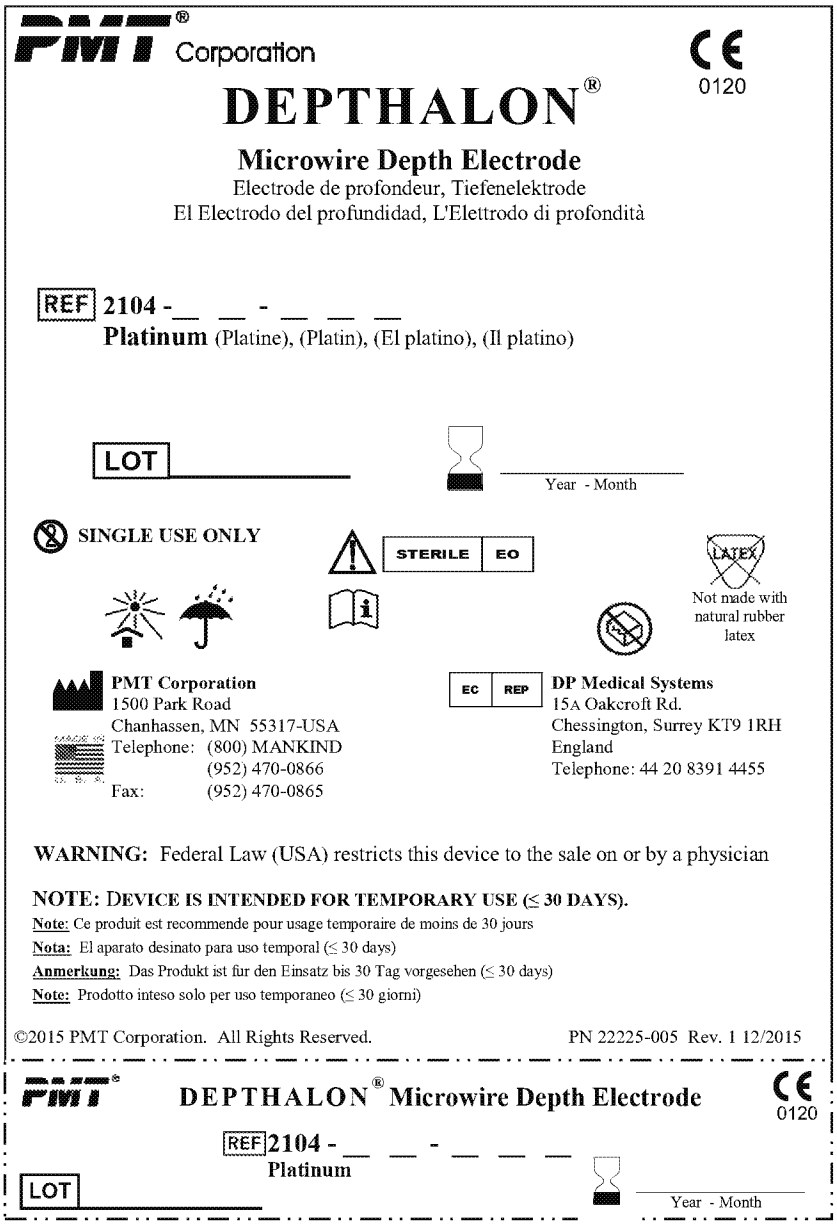
Sterile Depthalon Electrode Box Label Model 2104 – Platinum Microwire



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Non-sterile Depthalon Electrode Box Label Model 2104 – Platinum MicroWire

PMT® Corporation

CE 0120

DEPTHALON®

Microwire Depth Electrode

Electrode de profondeur, Tiefenelektrode
El Electrodo del profundidad, L'Elettrodo di profondità

REF 2104 -__ __ - __ __ __

Platinum (Platine), (Platin), (El platino), (Il platino)

LOT _____

NON STERILE

SINGLE USE ONLY

LATEX
Not made with natural rubber latex

PMT Corporation
1500 Park Road
Chanhassen, MN 55317-USA
Telephone: (800) MANKIND
(952) 470-0866
Fax: (952) 470-0865

EC REP **DP Medical Systems**
15A Oakcroft Rd.
Chessington, Surrey KT9 1RH
England
Telephone: 44 20 8391 4455

WARNING: Federal Law (USA) restricts this device to the sale on or by a physician

NOTE: DEVICE IS INTENDED FOR TEMPORARY USE (≤ 30 DAYS).
Note: Ce produit est recommende pour usage temporaire de moins de 30 jours
Nota: El aparato desinato para uso temporal (≤ 30 days)
Anmerkung: Das Produkt ist für den Einsatz bis 30 Tag vorgesehen (≤ 30 days)
Note: Prodotto inteso solo per uso temporaneo (≤ 30 giorni)

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PMT® **DEPTHALON® Microwire Depth Electrode** CE 0120

REF 2104 -__ __ - __ __ __
Platinum

LOT _____

NON-STERILE
NON STERILE, NO ESTÉRIL, NICHT STERIL

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

Records processed under FOIA Request 2024-2207; Released by CDRH on 11-13-2024

From: Kim Schmelzer [mailto:(b)(6)]
Sent: Wednesday, June 29, 2016 12:15 PM
To: Gutowski, Stacie
Cc: (b)(6)
Subject: Interactive Review for K151790

Stacie,

(b)(4)

I hope this answers your question. Please let me know if you have any further questions.

Thank you,
Kim Schmelzer | Quality Manager
PMT Corporation | Permark
1500 Park Road Chanhassen MN 55317 USA
D: +952.470.0866 | F: +952.470.0865
www.pmtcorp.com | www.permark.com

Description: pmt_logo

PMT Corporation CONFIDENTIAL:
The information contained in this email communication is confidential information intended only for the use of the addressee. Unauthorized use, disclosure or copying of this communication is strictly prohibited and may be unlawful. If you have received this communication in error, please notify us immediately by return email and destroy all copies of this communication, including all attachments.

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

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K151790/A001

FDA CDRH DMC

OCT 13 2015

Received

PMT®

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October 9, 2015

Department of Health & Human Services
Public Health Service Food and Drug Administration
Attn: Lisa McDonald
10903 New Hampshire Avenue
Document Control Room W066-0609
Silver Spring, MD 20993-0002

Reference: K151790 – PMT® Platinum Depthalon Depth Electrode

Ms. McDonald,

(b)(4)

This submission contains confidential commercial and trade secret information. We respectfully request that you give this notification the maximum protection provided by law.

If there are any questions or concerns, please contact me at 952-470-0866 or **(b)(6)**

Sincerely,

(b)(6)

Kim Schmelzer
Quality Manager
PMT Corporation

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

Records processed under FOIA Request 2024-2207; Released by CDRH on 11-13-2024

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

Form Approval
OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on page 5.

Date of Submission	User Fee Payment ID Number	FDA Submission Document Number *(if known)*
	(b)(4)	

SECTION A TYPE OF SUBMISSION

PMA	PMA & HDE Supplement	PDP	510(k)	Request for Feedback
☐ Original Submission	☐ Regular (180 day)	☐ Original PDP	☒ Original Submission:	☐ Pre-Submission
☐ Premarket Report	☐ Special	☐ Notice of Completion	☒ Traditional	☐ Informational Meeting
☐ Modular Submission	☐ Panel Track (PMA Only)	☐ Amendment to PDP	☐ Special	☐ Submision Issue Meeting
☐ Amendment	☐ 30-day Supplement		☐ Abbreviated (Complete section I, Page 5)	☐ Day 100 Meeting
☐ Report	☐ 30-day Notice		☐ Additional Information	☐ Agreement Meeting
☐ Report Amendment	☐ 135-day Supplement		☐ Third Party	☐ Determination Meeting
☐ Licensing Agreement	☐ Real-time Review			☐ Study Risk Determination
	☐ Amendment to PMA & HDE Supplement			☐ Other *(specify)*:
	☐ Other			

IDE	Humanitarian Device Exemption (HDE)	Class II Exemption Petition	Evaluation of Automatic Class III Designation (De Novo)	Other Submission
☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ 513(g)
☐ Amendment	☐ Amendment	☐ Additional Information	☐ Additional Information	☐ Other *(describe submission)*:
☐ Supplement	☐ Supplement			
	☐ Report			
	☐ Report Amendment			

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

SECTION B SUBMITTER, APPLICANT OR SPONSOR

Company / Institution Name	Establishment Registration Number *(if known)*		
PMT Corporation	2182979		
Division Name *(if applicable)*	**Phone Number *(including area code)***		
	952-470-0866		
Street Address	**FAX Number *(including area code)***		
1500 Park Road	952-470-0866		
City	**State / Province**	**ZIP/Postal Code**	**Country**
Chanhassen	MN	55317	USA
Contact Name			
Kim Schmelzer			
Contact Title	**Contact E-mail Address**		
Quality Manager	(b)(6)		

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

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

PSC Publishing Services (301) 443-6740 EF

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

Records processed under FOIA Request 2024-2207; Released by CDRH on 11-13-2024

SECTION D1 REASON FOR APPLICATION - PMA, PDP, OR HDE

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

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

- ☐ Location change:
  - ☐ Manufacturer
  - ☐ Sterilizer
  - ☐ Packager

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

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

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

- ☐ Response to FDA correspondence:

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

- ☐ Other Reason *(specify)*:

SECTION D2 REASON FOR APPLICATION - IDE

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

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

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

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

- ☐ Other Reason *(specify)*:

SECTION D3 REASON FOR SUBMISSION - 510(k)

- ☐ New Device
- ☒ Additional or Expanded Indications
- ☐ Change in Technology

- ☐ Other Reason *(specify)*:

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

Records processed under FOIA Request 2024-2207; Released by CDRH on 11-13-2024

SECTION E ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed

1	GZL	2		3		4	
5		6		7		8	

Summary of, or statement concerning, safety and effectiveness information

- [x] 510 (k) summary attached
- [x] 510 (k) statement

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

	510(k) Number	*Trade or Proprietary or Model Name*	*Manufacturer*
1	K082152	PMT Depthalon Depth Electrode Model 2102	PMT Corporation
2	K041604	Macro-Micro Electrodes	Ad-tech Corporation
3			
4			
5			
6			

SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification name

PMT Platinum Depthalon Depth Electrodes

	Trade or Proprietary or Model Name for This Device	Model Number
1	(b)(4)	
2		
3		
4		
5		5

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

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

Data Included in Submission

- [x] Laboratory Testing
- [ ] Animal Trials
- [ ] Human Trials

SECTION G PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS

Product Code	C.F.R. Section *(if applicable)*	Device Class
GZL	882.1330	[ ] Class I [x] Class II [ ] Class III [ ] Unclassified

Classification Panel

Neurology

Indications *(from labeling)*

The Platinum Depthalon® Depth Electrodes are intended for temporary (<30 day) use with recording, monitoring, and stimulation equipment for the recording, monitoring and stimulation of electrical signals in the subsurface of the brain.

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

Records processed under FOIA Request 2024-2207; Released by CDRH on 11-13-2024

Note: Submission of the information entered in Section H does not affect the need to submit device establishment registration.	FDA Document Number *(if known)*

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

(b)(4)

☐ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☐ Manufacturer ☐ Contract Manufacturer	☐ Contract Sterilizer ☐ Repackager / Relabeler
Company / Institution Name		Establishment Registration Number	
Division Name *(if applicable)*		Phone Number *(including area code)*	
Street Address		FAX Number *(including area code)*	
City	State / Province	ZIP Code	Country
Contact Name	Contact Title	Contact E-mail Address	

☐ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☐ Manufacturer ☐ Contract Manufacturer	☐ Contract Sterilizer ☐ Repackager / Relabeler
Company / Institution Name		Establishment Registration Number	
Division Name *(if applicable)*		Phone Number *(including area code)*	
Street Address		FAX Number *(including area code)*	
City	State / Province	ZIP Code	Country
Contact Name	Contact Title	Contact E-mail Address	

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

Records processed under FOIA Request 2024-2207; Released by CDRH on 11-13-2024

SECTION I — UTILIZATION OF STANDARDS

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

	Standards No.	Standards Organization	Standards Title	Version	Date
1	CFR Title 21 Part 820	FDA	Quality System Regulations	Current	
2	ISO 13485:2003	ISO	Quality System - Medical Device Particular Requirements for Application of 9001	2003	
3	BS/EN/ISO 14971:2012	ISO	Medical Devices - Application of Risk Management	2012	
4	(b)(4)				
5	IEC 60601-1 (b)(4)	IEC	Medical Electrical Equipment Part 1: General Requirements for basic Safety and Essential Performance	3rd	
6	CFR Title 21 Part 898	FDA	Performance Standard for Electrode Lead Wire and Patient Cables		
7			SEE ATTACHED SHEET FOR ADDITIONAL STANDARDS		

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

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF ADDRESS BELOW.

The burden time for this collection of information is estimated to average 0.5 hour per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
1350 Piccard Drive, Room 400
Rockville, MD 20850

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

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

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DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service

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

July 29, 2016

PMT Corporation
Kim Schmelzer
Quality Manager
1500 Park Road
Chanhassen, MN 55317

Re: K151790
Trade/Device Name: PMT Platinum Depthalon Depth Electrodes
Regulation Number: 21 CFR 882.1330
Regulation Name: Depth Electrode
Regulatory Class: Class II
Product Code: GZL
Dated: June 9, 2016
Received: October 9, 2015

Dear Kim Schmelzer:

This letter corrects our substantially equivalent letter of July 14, 2016.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

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

Records processed under FOIA Request 2024-2207; Released by CDRH on 11-13-2024

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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

Sincerely,

William J. Heetderks -A

Digitally signed by William J. Heetderks -A
DN: c=US, o=U.S. Government, ou=HHS, ou=NIH, ou=People, 0.9.2342.19200300.100.1.1=0010149848, cn=William J. Heetderks -A
Date: 2016.07.29 11:32:59 -04'00'

for Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

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

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PMT®

1500 Park Road • Chanhassen, MN 55317 USA • Phone (952) 470-0866 • Fax (952) 470-0865 • www.pmtcorp.com

Indications for Use Statement

510(k) Number (if known): K151790

Device Name

PMT® Platinum Depthalon® Depth Electrodes

Indications for Use

The Platinum Depthalon® Depth Electrodes are intended for temporary (<30 day) use with recording, monitoring, and stimulation equipment for the recording, monitoring and stimulation of electrical signals in the subsurface of the brain.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use __X___ OR Over the Counter Use_____
(Per 21 CFR 801.109

(Optimal Format 1-2-96)

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

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From: Le, Ponleiy * [Ponleiy.Le@fda.hhs.gov]
Sent: 10/9/2015 6:14:58 PM
To: (b)(6)
CC: DCCLetters [DCCLetters@fda.hhs.gov]
Subject: K151790/S001 ACK LETTER
Attachments: Acknowledgment%20Letter.pdf

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

Records processed under FOIA Request 2024-2207; Released by CDRH on 11-13-2024

DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

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

Acknowledgment Letter

10/09/2015

KIM SCHMELZER
QUALITY MANAGER
PMT CORPORATION
1500 PARK RD
CHANHASSEN, MN 55317
United States

Dear KIM SCHMELZER:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has received your submission. This submission has been assigned the unique document control number below. Please refer prominently to this number in all future correspondence that relates to this submission. Failure to do so may result in processing delays. If the 'Applicant' identified below is incorrect, please notify the 510(k) Staff immediately at (301) 796-5640.

Submission Number: K151790/S001
Received: 10/09/2015
Applicant: PMT CORPORATION
Device: (b)(4)

We will notify you when the processing of your 510(k) has been completed or if any additional information is required. YOU MAY NOT PLACE THIS DEVICE INTO COMMERCIAL DISTRIBUTION UNTIL YOU RECEIVE A LETTER FROM FDA ALLOWING YOU TO DO SO.

If any additional information is required, we will notify you via an Acceptance Review communication, Additional Information (AI) request, and/or Interactive Review communication. For additional information on these types of communication and their effect on the FDA Review Clock (if any), please refer to the following guidance documents:

"FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Goals" at http://www.fda.gov/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm089735.htm.

"Refuse to Accept Policy for 510(k)s" at http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM315014.pdf.

"Types of Communication During the Review of Medical Device Submissions" at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm341918.htm.

When responding to an information request that stops the FDA Review Clock (e.g., an AI request or refuse to accept (RTA) decision), you must submit your complete response with valid electronic copy (eCopy) to the Document Control Center (DCC) at the above address. An incomplete response or a response sent any other way (e.g., to another address or via email) will **not** be considered an official response and will not restart the FDA Review Clock. For more information about FDA's eCopy program, including the new technical standards for an eCopy, refer to the guidance document, "eCopy Program for Medical Device Submissions" at http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM313794.pdf

Record processed under FOIA Request 2024-2207, Released by CDRH on 11-18-2024

To learn more about the overall 510(k) submission process, please refer to our website at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/default.htm.

If you have any procedural or policy questions, please refer to our website at http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm or contact the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041, (301) 796-7100, or *DICE@fda.hhs.gov*.

Sincerely yours,

Marjorie Shulman
Director, 510(k) Program
Premarket Notification (510(k)) Staff
Office of Device Evaluation
Center for Devices and Radiological Health

Records processed under FOIA Request 2024-2207; Released by CDRH on 11-13-2024

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Indications for Use Statement

(b)(4)

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

ORIGINAL
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PMT CORPORATION

Document type: *Technical Report*	Document No. (b)(4)	Page 1 of 8
Document title: (b)(4)	Effective Date 7/21/98	Current Rev. (b)(4)

(b)(4)

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

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(b)(4)

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(b)(4)

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

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From: Smith, Alysia * [Alysia.Smith@fda.hhs.gov]
Sent: 7/2/2015 9:11:50 PM
To: (b)(6)
CC: DCCLetters [DCCLetters@fda.hhs.gov]
Subject: K151790 eCopy Hold Letter with Attachment
Attachments: K151790 eCopy Hold Letter.pdf; K151790 ATTACHMENT.pdf

Thank You,

Alysia Smith
Records Management Specialist- 510K Staff
FDA/DCC
White Oak, Silver Spring MD
Center for Devices and Radiological Health

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

Records processed under FOIA Request 2024-2207; Released by CDRH on 11-13-2024

DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

eCopy Hold Letter

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

07/01/2015

KIM SCHMELZER
QUALITY MANAGER
PMT CORPORATION
1500 PARK RD
CHANHASSEN, MN 55317
United States

Dear KIM SCHMELZER:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has received your submission. This submission has been assigned the unique document control number below. Failure to reference this assigned number in future correspondence may result in processing delays.

Submission Number: K151790
Received: 07/01/2015
Applicant: PMT CORPORATION
Device: (b)(4)

The Federal Food, Drug, and Cosmetic Act (the Act), as amended by section 1136 of the Food and Drug Administration Safety and Innovation Act (FDASIA), authorizes FDA to require an electronic copy (eCopy) for certain types of submissions. **You have received this letter because you have either not provided an eCopy or you provided an eCopy that failed the loading process because it did not meet the technical standards.** If you provided an eCopy that failed the loading process, then please see the attached document that identifies all reasons for the failure that need to be addressed. To understand the reasons for your eCopy failure, please refer to the eCopy guidance document, "eCopy Program for Medical Device Submissions" at http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM313794.pdf.

Please write the specific submission number identified above AND "Replacement eCopy" directly on the CD (or other media) and send that with a paper copy of your cover letter (revised if applicable) to the CDRH Document Control Center (DCC) at the address below.

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

When your Replacement eCopy has been received and been verified as a valid eCopy, review of this submission will start as of that date.

If you have any questions concerning this letter, please contact the eCopy Program Coordinators at (240) 402-3717 or at CDRH-eCopyinfo@fda.hhs.gov.

Sincerely yours,

Center for Devices and Radiological Health

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

Records processed under FOIA Request 2024-2207; Released by CDRH on 11-13-2024

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

Form Approval
OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on page 5.

Date of Submission	User Fee Payment ID Number	FDA Submission Document Number *(if known)*
	(b)(4)	

SECTION A TYPE OF SUBMISSION

PMA	PMA & HDE Supplement	PDP	510(k)	Request for Feedback
☐ Original Submission	☐ Regular (180 day)	☐ Original PDP	☒ Original Submission:	☐ Pre-Submission
☐ Premarket Report	☐ Special	☐ Notice of Completion	☒ Traditional	☐ Informational Meeting
☐ Modular Submission	☐ Panel Track (PMA Only)	☐ Amendment to PDP	☐ Special	☐ Submision Issue Meeting
☐ Amendment	☐ 30-day Supplement		☐ Abbreviated (Complete section I, Page 5)	☐ Day 100 Meeting
☐ Report	☐ 30-day Notice		☐ Additional Information	☐ Agreement Meeting
☐ Report Amendment	☐ 135-day Supplement		☐ Third Party	☐ Determination Meeting
☐ Licensing Agreement	☐ Real-time Review			☐ Study Risk Determination
	☐ Amendment to PMA & HDE Supplement			☐ Other *(specify)*:
	☐ Other			

IDE	Humanitarian Device Exemption (HDE)	Class II Exemption Petition	Evaluation of Automatic Class III Designation (De Novo)	Other Submission
☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ 513(g)
☐ Amendment	☐ Amendment	☐ Additional Information	☐ Additional Information	☐ Other *(describe submission)*:
☐ Supplement	☐ Supplement			
	☐ Report			
	☐ Report Amendment			

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

SECTION B SUBMITTER, APPLICANT OR SPONSOR

Company / Institution Name	Establishment Registration Number *(if known)*		
PMT Corporation	2182979		
Division Name *(if applicable)*	Phone Number *(including area code)*		
	952-470-0866		
Street Address	FAX Number *(including area code)*		
1500 Park Road	952-470-0866		
City	State / Province	ZIP/Postal Code	Country
Chanhassen	MN	55317	USA
Contact Name			
Kim Schmelzer			
Contact Title	Contact E-mail Address		
Quality Manager	(b)(6)		

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

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

PSC Publishing Services (301) 443-6740 EF

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

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SECTION D1 REASON FOR APPLICATION - PMA, PDP, OR HDE

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

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

- ☐ Location change:
  - ☐ Manufacturer
  - ☐ Sterilizer
  - ☐ Packager

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

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

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

- ☐ Response to FDA correspondence:

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

☐ Other Reason *(specify)*:

SECTION D2 REASON FOR APPLICATION - IDE

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

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

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

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

☐ Other Reason *(specify)*:

SECTION D3 REASON FOR SUBMISSION - 510(k)

- ☐ New Device
- ☒ Additional or Expanded Indications
- ☐ Change in Technology

☐ Other Reason *(specify)*:

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

Records processed under FOIA Request 2024-2207; Released by CDRH on 11-13-2024

SECTION E ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed

1	GZL	2		3		4	
5		6		7		8	

Summary of, or statement concerning, safety and effectiveness information

- [X] 510 (k) summary attached
- [X] 510 (k) statement

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

	510(k) Number		*Trade or Proprietary or Model Name*		*Manufacturer*
1	K082152	1	PMT Depthalon Depth Electrode Model 2102	1	PMT Corporation
2	K041604	2	Macro-Micro Electrodes	2	Ad-tech Corporation
3		3		3	
4		4		4	
5		5		5	
6		6		6	

SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification name

(b)(4)

	Trade or Proprietary or Model Name for This Device	Model Number
1	(b)(4)	
2		
3		
4		
5		5

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

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

Data Included in Submission

- [X] Laboratory Testing
- [ ] Animal Trials
- [ ] Human Trials

SECTION G PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS

Product Code	C.F.R. Section *(if applicable)*	Device Class
GZL	882.1330	[ ] Class I [X] Class II
Classification Panel: Neurology		[ ] Class III [ ] Unclassified

Indications *(from labeling)*

(b)(4)

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

Records processed under FOIA Request 2024-2207; Released by CDRH on 11-13-2024

Note: Submission of the information entered in Section H does not affect the need to submit device establishment registration.	FDA Document Number *(if known)*

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

(b)(4)

☐ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☐ Manufacturer ☐ Contract Manufacturer	☐ Contract Sterilizer ☐ Repackager / Relabeler
Company / Institution Name		Establishment Registration Number	
Division Name *(if applicable)*		Phone Number *(including area code)*	
Street Address		FAX Number *(including area code)*	
City	State / Province	ZIP Code	Country
Contact Name	Contact Title	Contact E-mail Address	

☐ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☐ Manufacturer ☐ Contract Manufacturer	☐ Contract Sterilizer ☐ Repackager / Relabeler
Company / Institution Name		Establishment Registration Number	
Division Name *(if applicable)*		Phone Number *(including area code)*	
Street Address		FAX Number *(including area code)*	
City	State / Province	ZIP Code	Country
Contact Name	Contact Title	Contact E-mail Address	

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

Records processed under FOIA Request 2024-2207; Released by CDRH on 11-13-2024

SECTION I — UTILIZATION OF STANDARDS

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

	Standards No.	Standards Organization	Standards Title	Version	Date
1	CFR Title 21 Part 820	FDA	Quality System Regulations	Current	
2	ISO 13485:2003	ISO	Quality System - Medical Device Particular Requirements for Application of 9001	2003	
3	BS/EN/ISO 14971:2012	ISO	Medical Devices - Application of Risk Management	2012	
4	(b)(4)				
5	IEC 60601-1 (b)(4)	IEC	Medical Electrical Equipment Part 1: General Requirements for basic Safety and Essential Performance	3rd	
6	CFR Title 21 Part 898	FDA	Performance Standard for Electrode Lead Wire and Patient Cables		
7			SEE ATTACHED SHEET FOR ADDITIONAL STANDARDS		

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

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF ADDRESS BELOW.

The burden time for this collection of information is estimated to average 0.5 hour per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
1350 Piccard Drive, Room 400
Rockville, MD 20850

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

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

Records processed under FOIA Request 2024-2207; Released by CDRH on 11-13-2024

PMT®

1500 Park Road • Chanhassen, MN 55317 USA • Phone (952) 470-0866 • Fax (952) 470-0865 • www.pmtcorp.com

June 25, 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

Reference: K802152 – PMT® Depthalon® Depth Electrode (b)(4)

To Whom It May Concern:

PMT hereby submits this pre-market notification (b)(4) for Depthalon Depth Electrode Model 2102 family PMT manufactures and markets.

This submission contains confidential commercial and trade secret information. We respectfully request that you give this notification the maximum protection provided by law.

Thank you in advance for your consideration of this application. If there are any questions, please contact me at 952-470-0866 or (b)(6)

Attached is a copy of our Medical Device User Fee cover sheet for this submission. The PIN is (b)(4)

Sincerely,

HARD COPIES ARE SIGNED

Kim Schmelzer
Quality Manager
PMT Corporation

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

Records processed under FOIA Request 2024-2207; Released by CDRH on 11-13-2024

(b)(4)

PMT CORPORATION

Platinum Depthalon Depth Electrode

(b)(4)

(b)(4) Test

(b)(4)

April 22, 2014

(b)(4)

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

Records processed under FOIA Request 2024-2207; Released by CDRH on 11-13-2024

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

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(b)(4)

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

From: Gutowski, Stacie
Sent: Friday, July 31, 2015 2:01 PM
To: (b)(6)
Subject: RE: K151790 is on Hold Pending Your Response

Hello Kim,

(b)(4)

Please let me know if this is still unclear, or if you have any additional questions.

Sincerely,
Stacie Gutowski, Ph.D.
Biomedical Engineer
ODE/DNPMD/NSDB
White Oak Building #66, Room 1436
10903 New Hampshire Avenue
Silver Spring, MD 20993
(240) 402-6032
Stacie.Gutowski@fda.hhs.gov

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received:
https://www.research.net/s/cdrhcustomerservice?O=400&D=460&B=462&E=&S=E

From: Kim Schmelzer [mailto: (b)(6)
Sent: Friday, July 31, 2015 1:06 PM
To: Gutowski, Stacie
Subject: RE: K151790 is on Hold Pending Your Response

Stacie,

Thank you for your prompt response.

One quick question: (b)(4)
(b)(4)

Kim Schmelzer | Quality Manager
PMT Corporation | Permark
1500 Park Road Chanhassen MN 55317 USA
D: +952.470.0866 | F: +952.470.0865
Toll Free: 1.800.MANKIND (626-5463)
www.pmtcorp.com | www.permark.com

Description: pmt_logo

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From: Gutowski, Stacie [mailto:Stacie.Gutowski@fda.hhs.gov]
Sent: Friday, July 31, 2015 11:55 AM
To: Kim Schmelzer
Subject: RE: K151790 is on Hold Pending Your Response

Hello Kim,
Thank you for your email, I'm happy to answer your questions.

(b)(4)

Please don't hesitate to contact me if you have any additional questions.

Sincerely,
Stacie Gutowski, Ph.D.
Biomedical Engineer

Records processed under FOIA Request 2024-2207; Released by CDRH on 11-13-2024

ODE/DNPMD/NSDB
White Oak Building #66, Room 1436
10903 New Hampshire Avenue
Silver Spring, MD 20993
(240) 402-6032
Stacie.Gutowski@fda.hhs.gov

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received:
https://www.research.net/s/cdrhcustomerservice?O=400&D=460&B=462&E=&S=E

From: Kim Schmelzer [mailto:(b)(6)
Sent: Friday, July 31, 2015 12:25 PM
To: Gutowski, Stacie
Subject: RE: K151790 is on Hold Pending Your Response

Stacie,

(b)(4)

If you could please answer those two questions for me I would greatly appreciate it.

Kim Schmelzer | Quality Manager
PMT Corporation | Permark
1500 Park Road Chanhassen MN 55317 USA
D: +952.470.0866 | F: +952.470.0865
Toll Free: 1.800.MANKIND (626-5463)
www.pmtcorp.com | www.permark.com

Description: pmt_logo

PMT Corporation CONFIDENTIAL:
The information contained in this email communication is confidential information intended only for the use of the addressee. Unauthorized use, disclosure or copying of this communication is strictly prohibited and may be unlawful. If you have received this communication in error, please notify us immediately by return email and destroy all copies of this communication, including all attachments.

From: Stacie Gutowski [mailto:stacie.gutowski@fda.hhs.gov]
Sent: Friday, July 31, 2015 10:36 AM
To: (b)(6)
Cc: Stacie Gutowski
Subject: K151790 is on Hold Pending Your Response

July 31, 2015 **Acceptance Review Notification - Refuse To Accept (RTA)**

We have completed the administrative acceptance review of your premarket notification (510(k)) submission K151790. Our review indicates that your 510(k) submission does not meet the criteria established for administrative completeness. Thus, we regret to inform you that we are unable to conduct a substantive review of your submission at this time and are placing it on RTA hold.

Please submit two copies of your response (1 eCopy and 1 paper copy), referencing the 510(k) number K151790, addressing the elements identified as missing or inconsistent in the attached checklist to:

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

FDA will permit your 510(k) submission to remain on hold for a maximum of 180 days from the date of this email. If you do not correct the missing or inconsistent elements identified in the checklist within 180 days, we will consider this 510(k) submission to be withdrawn, and we will delete it from our review system.

Upon receipt of the requested information, FDA will conduct another administrative review of your 510(k) submission.

Should you have questions about this email, you may contact Stacie Gutowski, the lead reviewer assigned to your 510(k) submission.

For additional information regarding the Refuse to Accept Policy for 510(k)s please refer to the guidance document available at http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM315014.pdf.

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K157190
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Device Trade Name: Depthalon Depth Electrode
Contact Name: Kim Schmelzer

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Hi Kim,

(b)(4)

Stacie Gutowski, Ph.D.
Biomedical Engineer
ODE/DNPMD/NSDB
WO 66, Rm 2656
10903 New Hampshire Avenue
Silver Spring, MD 20993
(240) 402-6032
Stacie.Gutowski@fda.hhs.gov

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From: Kim Schmelzer [mailto:(b)(6)
Sent: Thursday, July 07, 2016 9:54 AM
To: Gutowski, Stacie
Subject: RE: (b)(4) needed for K151790

Stacie,

(b)(4)

Thank you,
Kim Schmelzer | Quality Manager
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www.pmtcorp.com | www.permark.com

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From: Gutowski, Stacie [mailto:Stacie.Gutowski@fda.hhs.gov]
Sent: Thursday, July 07, 2016 6:42 AM
To: Kim Schmelzer
Cc: k151790@docs.fda.gov
Subject: RE: (b)(4) needed for K151790

Hi Kim,

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Stacie Gutowski, Ph.D.
Biomedical Engineer
ODE/DNPMD/NSDB
WO 66, Rm 2656
10903 New Hampshire Avenue
Silver Spring, MD 20993
(240) 402-6032
Stacie.Gutowski@fda.hhs.gov

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From: Kim Schmelzer [mailto:(b)(6)
Sent: Wednesday, July 06, 2016 4:55 PM
To: Gutowski, Stacie
Cc: (b)(6)
Subject: RE: (b)(4) needed for K151790

Stacie,

Regarding you first question;

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Let me know if you have any further questions on this.

Thank you,
Kim Schmelzer | Quality Manager
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Sent: Wednesday, July 06, 2016 12:20 PM
To: Kim Schmelzer
Subject: RE: (b)(4) needed for K151790

Hello Kim,

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Stacie Gutowski, Ph.D.
Biomedical Engineer
ODE/DNPMD/NSDB
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From: Kim Schmelzer [mailto:(b)(6)
Sent: Wednesday, July 06, 2016 12:05 PM
To: Gutowski, Stacie
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Stacie,

(b)(4)

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From: Gutowski, Stacie [mailto:Stacie.Gutowski@fda.hhs.gov]
Sent: Wednesday, July 06, 2016 10:12 AM
To: Kim Schmelzer
Cc: k151790@docs.fda.gov
Subject: (b)(4) needed for K151790

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

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Department of Health & Human Services **Food and Drug Administration**

MEMORANDUM

Date: July 12, 2016

To: Stacie Gutowski, PhD
Team Leader
DNPMD/NSDB

From: Hyung Lee, PhD
Sterility Reviewer
DNPMD/NSDB

Cc: The Record

Device Name: Platinum Depthalon® Depth Electrodes (b)(5)
(b)(5)

Sponsor: PMT, Corp.

Re: Sponsor's Responses to Clearance for Depthalon® Depth Electrodes

(b)(5)

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(b)(5)

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

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(b)(4)

PMT CORPORATION

Platinum Depthalon Depth Electrode
Lot No.: (b)(4)

(b)(4) Test

(b)(4)

(GLP)

May 19, 2014

(b)(4)

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

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Hi Kim,

(b)(4)

Stacie Gutowski, Ph.D.
Biomedical Engineer
ODE/DNPMD/NSDB
WO 66, Rm 2656
10903 New Hampshire Avenue
Silver Spring, MD 20993
(240) 402-6032
Stacie.Gutowski@fda.hhs.gov

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From: Kim Schmelzer [mailto: (b)(6)
Sent: Wednesday, July 06, 2016 4:55 PM
To: Gutowski, Stacie
Cc: (b)(6)
Subject: RE: (b)(4) needed for K151790

Stacie,

Regarding you first question;

(b)(4)

Let me know if you have any further questions on this.

Thank you,
Kim Schmelzer | Quality Manager
PMT Corporation | Permark
1500 Park Road Chanhassen MN 55317 USA
D: +952.470.0866 | F: +952.470.0865
www.pmtcorp.com | www.permark.com

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From: Gutowski, Stacie [mailto:Stacie.Gutowski@fda.hhs.gov]
Sent: Wednesday, July 06, 2016 12:20 PM
To: Kim Schmelzer
Subject: RE: (b)(4) needed for K151790

Hello Kim,

(b)(4)

Stacie Gutowski, Ph.D.
Biomedical Engineer
ODE/DNPMD/NSDB
WO 66, Rm 2656
10903 New Hampshire Avenue

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

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Stacie.Gutowski@fda.hhs.gov

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From: Kim Schmelzer [mailto: (b)(6)
Sent: Wednesday, July 06, 2016 12:05 PM
To: Gutowski, Stacie
Subject: RE: (b)(4) needed for K151790

Stacie,

(b)(4)

Thank you,
Kim Schmelzer | Quality Manager
PMT Corporation | Permark
1500 Park Road Chanhassen MN 55317 USA
D: +952.470.0866 | F: +952.470.0865
www.pmtcorp.com | www.permark.com

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From: Gutowski, Stacie [mailto:Stacie.Gutowski@fda.hhs.gov]
Sent: Wednesday, July 06, 2016 10:12 AM
To: Kim Schmelzer
Cc: k151790@docs.fda.gov
Subject: (b)(4) needed for K151790

Hello Kim,

(b)(4)

Stacie Gutowski, Ph.D.
Biomedical Engineer
ODE/DNPMD/NSDB
WO 66, Rm 2656
10903 New Hampshire Avenue
Silver Spring, MD 20993
(240) 402-6032
Stacie.Gutowski@fda.hhs.gov

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Indications for Use Statement

510(k) Number (if known): K151790

Device Name

PMT® Platinum Depthalon® Depth Electrodes

Indications for Use

The Platinum Depthalon® Depth Electrodes are intended for temporary (<30 day) use with recording, monitoring, and stimulation equipment for the recording, monitoring and stimulation of electrical signals in the subsurface of the brain.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use __X___ OR Over the Counter Use_____
(Per 21 CFR 801.109

(Optimal Format 1-2-96)

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

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Traditional or Abbreviated 510(k)

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1. Medical Device User Fee Cover Sheet

Please see the attached copy.

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

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2. CDRH Premarket Review Submission Cover Sheet

Please see the attached copy.

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

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3. 510(K) Cover Letter

Please see the attached cover letter.

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

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4. Indications for Use Statement

Please see the attached Indications for Use Statement

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5. 510(k) Summary or 510(k) Statement

Please see the attached 510(k) Summary.

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

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6. Truthful and Accuracy Statement

Please see the following page for the Truthful and Accurate Statement

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

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Truthful and Accurate Statement

[As required by 21 CFR 807.87(j)]

I certify that, in my capacity as Quality Manager of PMT, I believe to the best of my knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.

HARD COPIES HAVE SIGNATURES
Kim Schmelzer

HARD COPIES HAVE DATES
Date

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

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7. Class III Summary and Certification

This Section Does Not Apply.

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

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8. Financial Certification or Disclosure Statement

This Section Does Not Apply.

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9. Summary Reports

(b)(4)

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10. Executive Summary

(b)(4)

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11. Device Description

(b)(4)

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12. Substantial Equivalence Discussion

(b)(4)

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

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13. Proposed Labeling

Please see Exhibit A for the proposed Instruction Manual, Product Label, and Carton Label.

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

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14. Sterilization and Shelf Life

(b)(4)

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

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15. Biocompatibility

(b)(4)

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16. Software

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17. Electromagnetic Compatibility and Electrical Safety

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18. Performance Testing

(b)(4)

Please see Exhibit D for performance testing conducted by PMT corporation.

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

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19. Performance Animal

This Section Does Not Apply

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

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20. Performance Clinical

This Section Does Not Apply

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21. Others

This Section Does Not Apply

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

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Exhibit A **Packaging, Labeling and Instruction Manual**

Page 37 Packaging Description

Page 38 Labeling

Page 44 Instruction Manual (IFU)

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Exhibit B **Biocompatibility**

Page 53 (b)(4) Protocol

Page 58 Report

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Exhibit C

(b)(4)

Page 427
Page 435

(b)(4)

Plan
Report

(b)(4)

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Exhibit D

Performance Testing

Page 470 (b)(4) Protocol
Page 476 Report
Page 494 (b)(4)
Validation Plan
Page 502 (b)(4)
Validation Report
Page 542 (b)(4)
Validation Plan – (b)(4)
Page 580 (b)(4) Validation
Protocol
Page 586 (b)(4) Validation
Report
Page 628 (b)(4) Validation
Protocol
Page 632 (b)(4) Validation
Report
Page 668 (b)(4)
(b)(4) Protocol
Page 674 (b)(4) Validation Report
Page 708 (b)(4) Validation Protocol
Page 712 Validation Report
Page 722 (b)(4) Validation Protocol, (b)(4)
(b)(4)
Page 728 (b)(4) Validation Report, (b)(4)
(b)(4)
Page 768 (b)(4) Validation Protocol, (b)(4)
(b)(4)
Page 774 (b)(4) Validation Report, (b)(4)
(b)(4)
Page 842 (b)(4) Test Protocol
Page 846 (b)(4)
Validation Report
Page 880 (b)(4) Validation Protocol
Page 886 Validation Report - (b)(4)
Page 924 Validation Report – (b)(4)
Page 954 (b)(4) Validation
Plan
Page 960 (b)(4) Validation Report
Page 1010 (b)(4) Test Protocol
Page 1016 Test Report

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Exhibit E **Depthalon Schematics**

Page 1051 Depthalon® Depth Electrode
Page 1053
Page 1055
Page 1057

(b)(4)

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

From: Gutowski, Stacie
Sent: Friday, July 31, 2015 12:55 PM
To: 'Kim Schmelzer'
Subject: RE: K151790 is on Hold Pending Your Response

Hello Kim,
Thank you for your email, I'm happy to answer your questions.

(b)(4)

Please don't hesitate to contact me if you have any additional questions.

Sincerely,
Stacie Gutowski, Ph.D.
Biomedical Engineer
ODE/DNPMD/NSDB
White Oak Building #66, Room 1436
10903 New Hampshire Avenue
Silver Spring, MD 20993
(240) 402-6032
Stacie.Gutowski@fda.hhs.gov

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https://www.research.net/s/cdrhcustomerservice?O=400&D=460&B=462&E=&S=E

From: Kim Schmelzer [mailto: (b)(6)
Sent: Friday, July 31, 2015 12:25 PM
To: Gutowski, Stacie
Subject: RE: K151790 is on Hold Pending Your Response

Stacie,

(b)(4)

If you could please answer those two questions for me I would greatly appreciate it.

Kim Schmelzer | Quality Manager
PMT Corporation | Permark
1500 Park Road Chanhassen MN 55317 USA
D: +952.470.0866 | F: +952.470.0865
Toll Free: 1.800.MANKIND (626-5463)
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From: Stacie Gutowski [mailto:stacie.gutowski@fda.hhs.gov]
Sent: Friday, July 31, 2015 10:36 AM
To: (b)(6)
Cc: Stacie Gutowski
Subject: K151790 is on Hold Pending Your Response

July 31, 2015 **Acceptance Review Notification - Refuse To Accept (RTA)**

We have completed the administrative acceptance review of your premarket notification (510(k)) submission K151790. Our review indicates that your 510(k)

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submission does not meet the criteria established for administrative completeness. Thus, we regret to inform you that we are unable to conduct a substantive review of your submission at this time and are placing it on RTA hold.

Please submit two copies of your response (1 eCopy and 1 paper copy), referencing the 510(k) number K151790, addressing the elements identified as missing or inconsistent in the attached checklist to:

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

FDA will permit your 510(k) submission to remain on hold for a maximum of 180 days from the date of this email. If you do not correct the missing or inconsistent elements identified in the checklist within 180 days, we will consider this 510(k) submission to be withdrawn, and we will delete it from our review system.

Upon receipt of the requested information, FDA will conduct another administrative review of your 510(k) submission.

Should you have questions about this email, you may contact Stacie Gutowski, the lead reviewer assigned to your 510(k) submission.

For additional information regarding the Refuse to Accept Policy for 510(k)s please refer to the guidance document available at http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM315014.pdf.

*** This is a system-generated email notification ***

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

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Dear Ms. Schmelzer,

Thank you for your email. The review team is looking over your questions and we should have a response for you within a day or two.

Sincerely,

Stacie Gutowski, Ph.D.

Biomedical Engineer

ODE/DNPMD/NSDB

WO 66, Rm 2656

10903 New Hampshire Avenue

Silver Spring, MD 20993

(240) 402-6032

Stacie.Gutowski@fda.hhs.gov<mailto:Stacie.Gutowski@fda.hhs.gov>

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https://www.research.net/s/cdrhcustomerservice?O=400&D=460&B=462&E=&S=E

From: Kim Schmelzer [mailto:(b)(6)

Sent: Monday, March 07, 2016 3:32 PM

To: Gutowski, Stacie

Subject: RE: K151790/S001 Question

Importance: High

Stacie,

Thank you for your reply. (b)(4)

(b)(4)

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

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(b)(4)

Thank you,

Kim Schmelzer | Quality Manager

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From: Gutowski, Stacie [mailto:Stacie.Gutowski@fda.hhs.gov]

Sent: Monday, March 07, 2016 1:17 PM

To: Kim Schmelzer

Cc: k151790@docs.fda.gov<mailto:k151790@docs.fda.gov>

Subject: RE: K151790/S001 Question

Dear Ms. Schmelzer,

(b)(4)

(b)(4) Please let me know if you have any further questions regarding this information.

Sincerely,

Stacie Gutowski, Ph.D.

Biomedical Engineer

ODE/DNPMD/NSDB

WO 66, Rm 2656

10903 New Hampshire Avenue

Silver Spring, MD 20993

(240) 402-6032

Stacie.Gutowski@fda.hhs.gov<mailto:Stacie.Gutowski@fda.hhs.gov>

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

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https://www.research.net/s/cdrhcustomerservice?O=400&D=460&B=462&E=&S=E

From: Kim Schmelzer [mailto: (b)(6)

Sent: Wednesday, March 02, 2016 2:51 PM

To: Gutowski, Stacie

Subject: RE: K151790/S001 Question

Stacie,

I hope this email finds you well.

(b)(4)

Thank you,

Kim Schmelzer | Quality Manager

PMT Corporation | Permark

1500 Park Road Chanhassen MN 55317 USA

D: +952.470.0866 | F: +952.470.0865

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Hello Kim,

(b)(4)

Stacie Gutowski, Ph.D.

Biomedical Engineer

ODE/DNPMD/NSDB

WO 66, Rm 2656

10903 New Hampshire Avenue

Silver Spring, MD 20993

(240) 402-6032

Stacie.Gutowski@fda.hhs.gov<mailto:Stacie.Gutowski@fda.hhs.gov>

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(b)(4)

(b)(4) TEST PROTOCOL

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

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FINAL GLP REPORT: (b)(4)

(b)(4)

(b)(4)

(b)(4)

*Test Performed for: PMT Corporation
1500 Park Road
Chanhassen, MN 55317

(b)(4)

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(b)(4)

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

Stacie – Thanks for working with Kim and myself on this 510(k) application.

(b)(4)

Thanks,

- Ben

Benjamin Osa
Neurosurgery Engineering Manager
PMT Corporation
1500 Park Road
Chanhassen, MN 55317
Email: (b)(6)
(P) 952-470-0866
(F) 952-470-0865

From: Gutowski, Stacie [mailto:Stacie.Gutowski@fda.hhs.gov]
Sent: Wednesday, June 15, 2016 8:01 PM
To: Ben Osa
Cc: k151790@docs.fda.gov; (b)(6)
Subject: RE: FDA requesting teleconference with your team

Hello Ben,
Thank you for understanding. The call-in information is below. We look forward to speaking with you at 2pm (eastern) on June 16.

(b)(4)

Stacie Gutowski, Ph.D.
Biomedical Engineer
ODE/DNPMD/NSDB
WO 66, Rm 2656
10903 New Hampshire Avenue
Silver Spring, MD 20993
(240) 402-6032
Stacie.Gutowski@fda.hhs.gov

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From: Ben Osa [mailto (b)(6)
Sent: Wednesday, June 15, 2016 5:29 PM
To: Gutowski, Stacie
Cc: k151790@docs.fda.gov; (b)(6)
Subject: RE: FDA requesting teleconference with your team

Hi Stacie – We can do a conference call tomorrow. Is there a dial in # for the call?

(b)(4)

Thanks for your help on this submittal.

- Ben

Benjamin Osa
Neurosurgery Engineering Manager
PMT Corporation
1500 Park Road
Chanhassen, MN 55317
Email: (b)(6)
(P) 952-470-0866
(F) 952-470-0865

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From: Gutowski, Stacie [mailto:Stacie.Gutowski@fda.hhs.gov]
Sent: Wednesday, June 15, 2016 3:58 PM
To: Ben Osa
Cc: k151790@docs.fda.gov; (b)(6)
Subject: RE: FDA requesting teleconference with your team

Hello Ben,

(b)(4)

Stacie Gutowski, Ph.D.
Biomedical Engineer
ODE/DNPMD/NSDB
WO 66, Rm 2656
10903 New Hampshire Avenue
Silver Spring, MD 20993
(240) 402-6032
Stacie.Gutowski@fda.hhs.gov

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From: Ben Osa [mailto: (b)(6)
Sent: Wednesday, June 15, 2016 4:52 PM
To: Gutowski, Stacie
Cc: k151790@docs.fda.gov; (b)(6)
Subject: FDA requesting teleconference with your team

Hi Stacie – (b)(6)

Is there a way we can do a teleconference on that date or a day soon afterwards?

Please let me know.

Thanks,

- Ben

Benjamin Osa
Neurosurgery Engineering Manager
PMT Corporation
1500 Park Road
Chanhassen, MN 55317
Email: (b)(6)
(P) 952-470-0866
(F) 952-470-0865

From: Gutowski, Stacie [mailto:Stacie.Gutowski@fda.hhs.gov]
Sent: Wednesday, June 15, 2016 1:47 PM
To: Kim Schmelzer
Cc: k151790@docs.fda.gov
Subject: FDA requesting teleconference with your team

Hello Kim,
(b)(4) Can we setup a teleconference meeting with you and your team tomorrow afternoon at 2pm (eastern time)? Please let me know if you are available.

Sincerely,
Stacie Gutowski, Ph.D.
Biomedical Engineer
ODE/DNPMD/NSDB
WO 66, Rm 2656
10903 New Hampshire Avenue
Silver Spring, MD 20993
(240) 402-6032
Stacie.Gutowski@fda.hhs.gov

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From: Muslimova, Valentina * [Valentina.Muslimova@fda.hhs.gov]
Sent: 6/9/2016 4:45:32 PM
To: (b)(6)
CC: DCCLetters [DCCLetters@fda.hhs.gov]
Subject: K151790/S002
Attachments: K151790 S002.pdf

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

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Acknowledgment Letter

6/9/2016

KIM SCHMELZER, QUALITY MANAGER
PMT CORPORATION
1500 PARK RD
CHANHASSEN, MN 55317
UNITED STATES

Dear KIM SCHMELZER:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has received your submission. This submission has been assigned the unique document control number below. All future correspondence regarding this submission should be identified prominently with the number assigned and should be submitted to the Document Control Center at the above letterhead address. Failure to do so may result in processing delays. If you believe the information identified below is incorrect, please notify the Program Operations Staff at (301) 796-5640.

Submission Number: K151790/S002
Received: 5/31/2016
Applicant: PMT CORPORATION
Device: PMT Platinum Depthalon Depth Electrode

We will notify you when the review of this submission has been completed or if any additional information is required. For information about CDRH review regulations and policies, please refer to http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm.

Sincerely yours,

Center for Devices and Radiological Health

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(b)(4) TEST PROTOCOL

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(b)(4)

FINAL GLP REPORT: (b)(4)

(b)(4)

*Test Performed for: PMT Corporation
1500 Park Road
Chanhassen, MN 55317

(b)(4)

Questions? Contact FDA/CDRH/OPEQ/OD at CDRH-FOISTAFF@fda.hhs.gov or 301-796-8118

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From: Mcdonald, Lisa * [Lisa.Mcdonald@fda.hhs.gov]
Sent: 10/13/2015 2:28:40 PM
To: (b)(6)
CC: DCCLetters [DCCLetters@fda.hhs.gov]
Subject: K151790/A001 ACK LETTER
Attachments: Acknowledgment_Letter-K151790_A001[1].pdf

Hi Kim

The changes has been updated in our database. Please see attached file.

Thank you,

Lisa McDonald
Technical Information Specialist – 510k Support Staff
Document Mail Center
Center for Devices and Radiological Health

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

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Acknowledgment Letter

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

10/13/2015

KIM SCHMELZER
QUALITY MANAGER
PMT CORPORATION
1500 PARK RD
CHANHASSEN, MN 55317
United States

Dear KIM SCHMELZER:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has received your submission. This submission has been assigned the unique document control number below. Please refer prominently to this number in all future correspondence that relates to this submission. Failure to do so may result in processing delays. If the 'Applicant' identified below is incorrect, please notify the 510(k) Staff immediately at (301) 796-5640.

Submission Number: K151790/A001
Received: 10/13/2015
Applicant: PMT CORPORATION
Device: PMT Platinum Depthalon Depth Electrode

We will notify you when the processing of your 510(k) has been completed or if any additional information is required. YOU MAY NOT PLACE THIS DEVICE INTO COMMERCIAL DISTRIBUTION UNTIL YOU RECEIVE A LETTER FROM FDA ALLOWING YOU TO DO SO.

If any additional information is required, we will notify you via an Acceptance Review communication, Additional Information (AI) request, and/or Interactive Review communication. For additional information on these types of communication and their effect on the FDA Review Clock (if any), please refer to the following guidance documents:

"FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Goals" at http://www.fda.gov/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm089735.htm.

"Refuse to Accept Policy for 510(k)s" at http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM315014.pdf.

"Types of Communication During the Review of Medical Device Submissions" at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm341918.htm.

When responding to an information request that stops the FDA Review Clock (e.g., an AI request or refuse to accept (RTA) decision), you must submit your complete response with valid electronic copy (eCopy) to the Document Control Center (DCC) at the above address. An incomplete response or a response sent any other way (e.g., to another address or via email) will **not** be considered an official response and will not restart the FDA Review Clock. For more information about FDA's eCopy program, including the new technical standards for an eCopy, refer to the guidance document, "eCopy Program for Medical Device Submissions" at http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM313794.pdf

Record processed under FOIA Request 2024-2207, Released by CDRH on 11-18-2024

To learn more about the overall 510(k) submission process, please refer to our website at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/default.htm.

If you have any procedural or policy questions, please refer to our website at http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm or contact the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041, (301) 796-7100, or *DICE@fda.hhs.gov*.

Sincerely yours,

Marjorie Shulman
Director, 510(k) Program
Premarket Notification (510(k)) Staff
Office of Device Evaluation
Center for Devices and Radiological Health

Records processed under FOIA Request 2024-2207; Released by CDRH on 11-13-2024

Dear Kim,

Thank you for your email. (b)(4) (b)(4) We are finalizing our review at this time and you should receive a more formal communication from us in the form of a letter within the next several business days.

Sincerely,

Stacie Gutowski, Ph.D.

Biomedical Engineer

ODE/DNPMD/NSDB

WO 66, Rm 2656

10903 New Hampshire Avenue

Silver Spring, MD 20993

(240) 402-6032

Stacie.Gutowski@fda.hhs.gov<mailto:Stacie.Gutowski@fda.hhs.gov>

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https://www.research.net/s/cdrhcustomerservice?O=400&D=460&B=462&E=&S=E

From: Kim Schmelzer [mailto:(b)(6)

Sent: Friday, December 04, 2015 1:17 PM

To: Gutowski, Stacie

Subject: RE: K151790/S001 Follow-up Information Request

Stacie,

I hope this email finds you well. (b)(4)

(b)(4)

Sincerley,

Kim Schmelzer | Quality Manager

PMT Corporation | Permark

1500 Park Road Chanhassen MN 55317 USA

D: +952.470.0866 | F: +952.470.0865

Toll Free: 1.800.MANKIND (626-5463)

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From: Gutowski, Stacie [mailto:Stacie.Gutowski@fda.hhs.gov]

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

Records processed under FOIA Request 2024-2207; Released by CDRH on 11-13-2024

Sent: Monday, October 19, 2015 5:37 PM

To: Kim Schmelzer

Cc: k151790@docs.fda.gov<mailto:k151790@docs.fda.gov>

Subject: RE: K151790/S001 Follow-up Information Request

Dear Kim,

Thank you for the additional information. We will incorporate this into our review.

Sincerely,

Stacie Gutowski, Ph.D.

Biomedical Engineer

ODE/DNPMD/NSDB

WO 66, Rm 2656

10903 New Hampshire Avenue

Silver Spring, MD 20993

(240) 402-6032

Stacie.Gutowski@fda.hhs.gov<mailto:Stacie.Gutowski@fda.hhs.gov>

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https://www.research.net/s/cdrhcustomerservice?O=400&D=460&B=462&E=&S=E

From: Kim Schmelzer [mailto: (b)(6)

Sent: Monday, October 19, 2015 5:04 PM

To: Gutowski, Stacie

Subject: RE: K151790/S001 Follow-up Information Request

Staci,

I hope you had a good weekend!

(b)(4)

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

Records processed under FOIA Request 2024-2207; Released by CDRH on 11-13-2024

(b)(4)

Let me know if you have any further questions or concerns.

Thank you,

Kim Schmelzer | Quality Manager

PMT Corporation | Permark

1500 Park Road Chanhassen MN 55317 USA

D: +952.470.0866 | F: +952.470.0865

Toll Free: 1.800.MANKIND (626-5463)

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From: Gutowski, Stacie [mailto:Stacie.Gutowski@fda.hhs.gov]

Sent: Friday, October 16, 2015 7:56 AM

To: Kim Schmelzer

Cc: k151790@docs.fda.gov<mailto:k151790@docs.fda.gov>

Subject: RE: K151790/S001 Follow-up Information Request

Dear Ms. Schmelzer,

(b)(4)

Please let me know if you have any questions.

Stacie Gutowski, Ph.D.

Biomedical Engineer

ODE/DNPMD/NSDB

WO 66, Rm 2656

10903 New Hampshire Avenue

Silver Spring, MD 20993

(240) 402-6032

Stacie.Gutowski@fda.hhs.gov<mailto:Stacie.Gutowski@fda.hhs.gov>

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https://www.research.net/s/cdrhcustomerservice?O=400&D=460&B=462&E=&S=E

From: Kim Schmelzer [mailto (b)(6)

Sent: Wednesday, October 14, 2015 2:15 PM

To: Gutowski, Stacie

Cc: k151790@docs.fda.gov<mailto:k151790@docs.fda.gov>

Subject: RE: K151790/S001 Follow-up Information Request

Stacie,

(b)(4)

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

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Let me know if you have any questions or need clarification.

Thank you,

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From: Gutowski, Stacie [mailto:Stacie.Gutowski@fda.hhs.gov]

Sent: Wednesday, October 14, 2015 11:38 AM

To: (b)(6)

Cc: k151790@docs.fda.gov<mailto:k151790@docs.fda.gov>

Subject: K151790/S001 Follow-up Information Request

Ms. Schmelzer,

We have completed administrative review of your submission (K151790) and have accepted the file for substantive review. (b)(4) (b)(4) Please see the attached RTA checklist for a description of the items needed for our review. Please email me with the updated documents, and be sure to cc the docs.fda.gov email address above on all future communications for this file. You only need to send the documentation for the items requested, no need to send the whole submission again.

Please let me know if you have any questions.

Stacie Gutowski, Ph.D.

Biomedical Engineer

ODE/DNPMD/NSDB

WO 66, Rm 2656

10903 New Hampshire Avenue

Silver Spring, MD 20993

(240) 402-6032

Stacie.Gutowski@fda.hhs.gov<mailto:Stacie.Gutowski@fda.hhs.gov>

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https://www.research.net/s/cdrhcustomerservice?O=400&D=460&B=462&E=&S=E

From: Stacie Gutowski [mailto:stacie.gutowski@fda.hhs.gov]

Sent: Wednesday, October 14, 2015 11:50 AM

To: (b)(6)

Cc: Gutowski, Stacie

Subject: K151790/S001 was Accepted

October 14, 2015

Acceptance Review Notification - Accepted

An administrative acceptance review was conducted on your premarket notification (510(k)) K151790/S001, and it was found to contain all of the necessary elements and information needed to proceed with the substantive review. We will contact you should we require any additional information during the course of the substantive review. The lead reviewer assigned to your submission is Stacie Gutowski.

*** This is a system-generated email notification ***

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

Records processed under FOIA Request 2024-2207; Released by CDRH on 11-13-2024

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Document type: TECHNICAL REPORT	Document No. (b)(4)	Page 1 of 5
Document title: (b)(4)	Effective Date 11/22/13	Current Rev. (b)(4)

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DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service

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

(b)(4)

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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

Sincerely yours,

William J. Heetderks -A

Digitally signed by William J. Heetderks -A
DN: c=US, o=U.S. Government, ou=HHS, ou=NIH, ou=People, 0.9.2342.19200300.100.1.1=0010149848, cn=William J. Heetderks -A
Date: 2016.07.14 11:27:56 -04'00'

for Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

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

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Document type: *Technical Report*	Document No. (b)(4)	Page 1 of 6
Document title: (b)(4)	Effective Date 8/15/09	Current Rev. (b)(4)

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DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service

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

K157190
PMT Corporation
Device Trade Name: Depthalon Depth Electrode
Contact Name: Kim Schmelzer

(b)(4)

Records processed under FOIA Request 2024-2207; Released by CDRH on 11-13-2024

(b)(4)

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Description of product packaging of the Depthalon Depth Electrodes

(b)(4)

PMT has conducted validations on the product packaging for sterility and packaging performance (b)(4)

(b)(4)

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

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Stacie,

(b)(4)

Let me know if you have any questions or need clarification.

Thank you,

Kim Schmelzer | Quality Manager

PMT Corporation | Permark

1500 Park Road Chanhassen MN 55317 USA

D: +952.470.0866 | F: +952.470.0865

Toll Free: 1.800.MANKIND (626-5463)

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

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From: Gutowski, Stacie [mailto:Stacie.Gutowski@fda.hhs.gov]
Sent: Wednesday, October 14, 2015 11:38 AM
To: (b)(6)
Cc: k151790@docs.fda.gov
Subject: K151790/S001 Follow-up Information Request

Ms. Schmelzer,

We have completed administrative review of your submission (K151790) and have accepted the file for substantive review. (b)(4) (b)(4) Please see the attached RTA checklist for a description of the items needed for our review. Please email me with the updated documents, and be sure to cc the docs.fda.gov email address above on all future communications for this file. You only need to send the documentation for the items requested, no need to send the whole submission again.

Please let me know if you have any questions.

Stacie Gutowski, Ph.D.

Biomedical Engineer

ODE/DNPMD/NSDB

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(240) 402-6032

<mailto:Stacie.Gutowski@fda.hhs.gov> Stacie.Gutowski@fda.hhs.gov

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https://www.research.net/s/cdrhcustomerservice?O=400&D=460&B=462&E=&S=E

From: Stacie Gutowski [<mailto:stacie.gutowski@fda.hhs.gov>

mailto:stacie.gutowski@fda.hhs.gov]

Sent: Wednesday, October 14, 2015 11:50 AM

To: <mailto: (b)(6)

Cc: Gutowski, Stacie

Subject: K151790/S001 was Accepted

October 14, 2015

Acceptance Review Notification - Accepted

An administrative acceptance review was conducted on your premarket notification (510(k)) K151790/S001, and it was found to contain all of the necessary elements and information needed to proceed with the substantive review. We will contact you should we require any additional information during the course of the substantive review. The lead reviewer assigned to your submission is Stacie Gutowski.

*** This is a system-generated email notification ***

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

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PMT CORPORATION

Document type: TECHNICAL REPORT	Document No. (b)(4)	Page 1 of 9
Document title: (b)(4)	Effective Date 1/30/15	Current Rev. (b)(4)

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

From: Kimberly Schmelzer [(b)(6)]
Sent: Thursday, June 16, 2016 2:35 PM
To: Gutowski, Stacie
Subject: RE: FDA requesting teleconference with your team

(b)(4)

Kim Schmelzer

Kim Schmelzer Sent from Mail for Windows 10

From: Gutowski, Stacie
Sent: Wednesday, June 15, 2016 8:01 PM
To: Ben Osa
Cc: k151790@docs.fda.gov; (b)(6)
Subject: RE: FDA requesting teleconference with your team

Hello Ben,
Thank you for understanding. The call-in information is below. We look forward to speaking with you at 2pm (eastern) on June 16.

(b)(4)

Stacie Gutowski, Ph.D.
Biomedical Engineer
ODE/DNPMD/NSDB
WO 66, Rm 2656
10903 New Hampshire Avenue
Silver Spring, MD 20993
(240) 402-6032
Stacie.Gutowski@fda.hhs.gov

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https://www.research.net/s/cdrhcustomerservice?O=400&D=460&B=462&E=&S=E

From: Ben Osa [mailto:(b)(6)]
Sent: Wednesday, June 15, 2016 5:29 PM
To: Gutowski, Stacie
Cc: k151790@docs.fda.gov; (b)(6)
Subject: RE: FDA requesting teleconference with your team

Hi Stacie -- We can do a conference call tomorrow. Is there a dial in # for the call?

(b)(4)

Thanks for your help on this submittal.

- Ben

Benjamin Osa
Neurosurgery Engineering Manager
PMT Corporation
1500 Park Road
Chanhassen, MN 55317
Email: (b)(6)
(P) 952-470-0866
(F) 952-470-0865

From: Gutowski, Stacie [mailto:Stacie.Gutowski@fda.hhs.gov]
Sent: Wednesday, June 15, 2016 3:58 PM
To: Ben Osa
Cc: k151790@docs.fda.gov; (b)(6)
Subject: RE: FDA requesting teleconference with your team

Hello Ben,

(b)(4)

Stacie Gutowski, Ph.D.
Biomedical Engineer
ODE/DNPMD/NSDB
WO 66, Rm 2656
10903 New Hampshire Avenue
Silver Spring, MD 20993
(240) 402-6032
Stacie.Gutowski@fda.hhs.gov

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From: Ben Osa [mailto:(b)(6)
Sent: Wednesday, June 15, 2016 4:52 PM
To: Gutowski, Stacie
Cc: k151790@docs.fda.gov; (b)(6)
Subject: FDA requesting teleconference with your team

Hi Stacie - (b)(6)

Is there a way we can do a teleconference on that date or a day soon afterwards?

Please let me know.

Thanks,

- Ben

Benjamin Osa
Neurosurgery Engineering Manager
PMT Corporation
1500 Park Road
Chanhassen, MN 55317
Email: (b)(6)
(P) 952-470-0866
(F) 952-470-0865

From: Gutowski, Stacie [mailto:Stacie.Gutowski@fda.hhs.gov]
Sent: Wednesday, June 15, 2016 1:47 PM
To: Kim Schmelzer
Cc: k151790@docs.fda.gov
Subject: FDA requesting teleconference with your team

Hello Kim,

(b)(4) Can we setup a teleconference meeting with you and your team tomorrow afternoon at 2pm (eastern time)? Please let me know if you are available.

Sincerely,
Stacie Gutowski, Ph.D.
Biomedical Engineer
ODE/DNPMD/NSDB
WO 66, Rm 2656
10903 New Hampshire Avenue
Silver Spring, MD 20993
(240) 402-6032
Stacie.Gutowski@fda.hhs.gov

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December 7, 2015</br></br> We have reviewed your submission K151790/S001 and have determined that additional information is required. Your file is being placed on hold pending a complete response to the attached deficiencies.

Please submit your response, referencing the submission number K151790/S001 to:

U.S. Food and Drug Administration

Center for Devices and Radiological Health

Document Control Center - WO66-G609

10903 New Hampshire Avenue

Silver Spring, MD 20993-0002

Please refer to the eCopy guidance at http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM313794.pdf for current information on the number of copies and the format (paper versus eCopy) you must submit.

Your response is due within 180 days from the date of this request, which is June 4, 2016. If a complete response is not received in CDRH's Document Control Center within 180 days, we will consider this submission to be withdrawn, and we will delete it from our review system.

You may not market this device until you have received a letter from FDA allowing you to do so. If you market the device without FDA clearance, you will be in violation of the Federal Food, Drug, and Cosmetic Act.

If you would like a meeting or teleconference with the review team and management to discuss your planned approach for responding to the attached deficiencies, please submit your request for feedback as a Submission Issue Q-Submission (Q-Sub). Please note that a Submission Issue Q-Sub does not take the place of a formal response to this email notification. As noted above, FDA will consider this submission to be withdrawn if FDA does not receive, in a submission to the Document Control Center, a complete response to all of the attached deficiencies within 180 calendar days of the date of this request.

Should you have questions about this email, you may contact Stacie Gutowski, the lead reviewer assigned to your submission.

 *** This is a system-generated email notification ***

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

Records processed under FOIA Request 2024-2207; Released by CDRH on 11-13-2024

Stacie,

(b)(4) Let me know if you have any questions.

Thank you,
Kim Schmelzer | Quality Manager
PMT Corporation | Permark
1500 Park Road Chanhassen MN 55317 USA
D: +952.470.0866 | F: +952.470.0865
www.pmtcorp.com | www.permark.com

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Document type: TECHNICAL REPORT	Document No. (b)(4)	Page 1 of 5
Document title: (b)(4) Validation Report	Effective Date 7/24/09	Current Rev. (b)(4)

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Records processed under FOIA Request 2024-2207; Released by CDRH on 11-13-2024

From: Kim Schmelzer [mailto:(b)(6)
Sent: Monday, July 11, 2016 4:34 PM
To: Gutowski, Stacie; k151790@docs.fda.gov
Cc: (b)(6)
Subject: RE: Interactive Review for K151790

Stacie,

(b)(4) Let me know if you have any questions.

Thank you,
Kim Schmelzer | Quality Manager
PMT Corporation | Permark
1500 Park Road Chanhassen MN 55317 USA
D: +952.470.0866 | F: +952.470.0865
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Processed by CDRH on Dec 11 2024

Memorandum

Biocompatibility Review

Date:	June 29, 2016
To:	Stacie Gutowski, Ph.D., Lead Reviewer DNPMD/NSDB
From:	Dhanya Williams, M.S. Biologist/Scientific Reviewer, DNPMD/NNDB
Reviewer Electronic Signature:	Dhanya K. Williams -S 2016.06.29 15:58:14 -04'00'
Subject:	K151790/S002
Applicant:	PMT Corporation 1500 Park Road Chanhassen, MN 55317
Device (Trade name):	PMT Platinum Depthalon® Depth Electrodes
Device (Regulation name):	Depth Electrode
Contact:	Kim Schmelzer, Quality Manager PMT Corporation 1500 Park Road Chanhassen, MN 55317 Phone: 952-470-0866 Fax: 952-470-0865 Email: (b)(6)
Recommendation:	**Substantially Equivalent (SESE)**

(b)(5)

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Document title: (b)(4)	Effective Date 01/31/14	Current Rev. (b)(4)

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Document type: TECHNICAL PROTOCOL	Document No. (b)(4)	Page 1 of 6
Document title: (b)(4)	Effective Date 11/18/2014	Current Rev. (b)(4)

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From: Kim Schmelzer [mailto:(b)(6)]

Sent: Monday, July 11, 2016 4:34 PM

To: Gutowski, Stacie; k151790@docs.fda.gov

Cc: (b)(6)

Subject: RE: Interactive Review for K151790

Stacie,

(b)(4)

(b)(4) Let me know if you have any questions.

Thank you,

Kim Schmelzer | Quality Manager

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PMT® Corporation
1500 PARK ROAD · CHANHASSEN, MN 55317 USA · PHONE (952) 470-0866 · 1-800-MANKIND · FAX (952) 470-0865

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Substantial Equivalence Comparison Table

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Executive Summary

a. Applicant Name and Address

PMT Corporation
1500 Park Road
Chanhassen, MN 55317

b. Contact Person

Kim Schmelzer,
Quality Manager

c. Telephone, Facsimile and Email

Phone: 952-470-0866 Fax: 952-470-0865 Email: (b)(6)

d. Signature: _____ **Date:** _____

e. Address – Manufacturing Site

PMT Corporation
1500 Park Road
Chanhassen, MN 55317

f. Address – Sterilization Site

(b)(4)

g. Establishment Registration Numbers

2182979
PMT Corporation (b)(4)

h. Device Description Summary

The PMT Platinum Depthalon® Depth Electrode is used intraoperatively for stimulating and monitoring recordable electrical brain activity or Electroencephalography (EEG) when less invasive methods do not provide the electrophysiology data necessary. This invasive intracranial, subdural electrode recording is performed through a burr hole leading into the brain. This method is necessary when the seizure focus is too small and / or too deep within the brain to produce a recordable EEG seizure.

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i. Device Description Summary Continued

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j. Indications

The Depthalon® Depth Electrodes are intended for temporary long term use (<30 day) use with recording, monitoring, and stimulation equipment for the recording, monitoring and stimulation of electrical signals in the subsurface of the brain.

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

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Device Description

a. Device Name

PMT Platinum Depthalon® Depth Electrodes

b. Classification Name

21 CFR 882.1330, Depth Electrode GZL

c. Classification

Class II

d. Common/Usual Name

Platinum Depth Electrodes

e. Technical Description

The PMT Platinum Depthalon Depth Electrode is used intraoperatively for stimulating and monitoring recordable electrical brain activity or Electroencephalography (EEG) when less invasive methods do not provide the electrophysiology data necessary. This invasive intracranial, subdural electrode recording is performed through a burr hole leading into the brain. This method is necessary when the seizure focus is too small and / or too deep within the brain to produce a recordable EEG seizure.

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f. Technical Description Continued

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(b)(6) Specification Sheet	3/11/2016	(b)(4)

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CC: DCCLetters [DCCLetters@fda.hhs.gov]
Subject: K151790/S002 ECOPY HOLD LETTER W/ ATTACHMENT
Attachments: K151790_S002.pdf

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DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
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eCopy Hold Letter

5/31/2016

KIM SCHMELZER, QUALITY MANAGER
PMT CORPORATION
1500 PARK RD
CHANHASSEN, MN 55317
UNITED STATES

Dear KIM SCHMELZER:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has received your submission. This submission has been assigned the unique document control number below. Failure to reference this assigned number in future correspondence may result in processing delays.

Submission Number: K151790/S002
Received: 5/31/2016
Applicant: PMT CORPORATION
Device: PMT Platinum Depthalon Depth Electrode

The Federal Food, Drug, and Cosmetic Act (the Act), as amended by section 1136 of the Food and Drug Administration Safety and Innovation Act (FDASIA), authorizes FDA to require an electronic copy (eCopy) for certain types of submissions. **You have received this letter because you have either not provided an eCopy or you provided an eCopy that failed the loading process because it did not meet the technical standards.** If you provided an eCopy that failed the loading process, then please see the attached document that identifies all reasons for the failure that need to be addressed. To understand the reasons for your eCopy failure, please refer to the eCopy guidance document, "eCopy Program for Medical Device Submissions" at http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM313794.pdf.

Please write the specific submission number identified above AND "Replacement eCopy" directly on the CD (or other media) and send that with a paper copy of your cover letter (revised if applicable) to the CDRH Document Control Center (DCC) at the address below.

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If you have any questions concerning this letter, please contact the eCopy Program Coordinators at (240) 402-3717 or at CDRH-eCopyinfo@fda.hhs.gov.

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Sincerely yours,

Center for Devices and Radiological Health

Attachment

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Attachment

Attachment for Submission Number(s):

K151790/S002

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Document type: Technical Report	Document No. (b)(4)	Page 1 of 11
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*Test Performed for: PMT Corporation
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Chanhassen, MN 55317

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Stacie,

(b)(4)

Let me know if you have any questions or need clarification.

Thank you,
Kim Schmelzer | Quality Manager
PMT Corporation | Permark
1500 Park Road Chanhassen MN 55317 USA
D: +952.470.0866 | F: +952.470.0865
Toll Free: 1.800.MANKIND (626-5463)
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From: Gutowski, Stacie [mailto:Stacie.Gutowski@fda.hhs.gov]
Sent: Wednesday, October 14, 2015 11:38 AM
To: (b)(6)
Cc: k151790@docs.fda.gov
Subject: K151790/S001 Follow-up Information Request

Ms. Schmelzer,
We have completed administrative review of your submission (K151790) and have accepted the file for substantive review. (b)(4) (b)(4) Please see the attached RTA checklist for a description of the items needed for our review. Please email me with the updated documents, and be sure to cc the docs.fda.gov email address above on all future communications for this file. You only need to send the documentation for the items requested, no need to send the whole submission again.
Please let me know if you have any questions.

Stacie Gutowski, Ph.D.
Biomedical Engineer
ODE/DNPMD/NSDB
WO 66, Rm 2656
10903 New Hampshire Avenue
Silver Spring, MD 20993
(240) 402-6032
Stacie.Gutowski@fda.hhs.gov

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From: Stacie Gutowski [mailto:stacie.gutowski@fda.hhs.gov]
Sent: Wednesday, October 14, 2015 11:50 AM
To: (b)(6)
Cc: Gutowski, Stacie
Subject: K151790/S001 was Accepted

October 14, 2015

Acceptance Review Notification - Accepted

An administrative acceptance review was conducted on your premarket notification (510(k)) K151790/S001, and it was found to contain all of the necessary elements and information needed to proceed with the substantive review. We will contact you should we require any additional information during the course of the substantive review. The lead reviewer assigned to your submission is Stacie Gutowski.

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

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From: Kim Schmelzer [mailto: (b)(6)

Sent: Wednesday, June 22, 2016 4:52 PM

To: Gutowski, Stacie

Cc: (b)(6)

Subject: Follow-up deficiency information for K151790 - Email #1

June 22, 2016

U.S. Food and Drug Administration

Center for Devices and Radiological Health

Document Control Center - WO66-G609

10903 New Hampshire Avenue

Silver Spring, MD 20993-0002

RE: K157190/S002

Device Name: PMT Platinum Depthalon(r) Depth Electrodes

Stacie Gutowski, Ph.D.,

The attached information located in this email is in response to your email received at PMT Corporation on Monday June 20, 2016 regarding the premarket 510(k) notification for PMT(r) Platinum Depthalon(r) Depth Electrodes. PMT Corporation at this time is responding to (b)(4) (b)(4) Should you have any questions please contact me.

Sincerely,

Thank you,

Kim Schmelzer | Quality Manager

PMT Corporation | Permark

1500 Park Road Chanhassen MN 55317 USA

D: +952.470.0866 | F: +952.470.0865

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Office Location
Business Address
Phone Number

Premarket Notification [510(k)] Review

Date: July 12, 2016

Reviewer: Stacie Gutowski, Ph.D.

Subject: Traditional 510(k)# K157190

Applicant: PMT Corporation

Device Trade Name: Depthalon Depth Electrode

Contact Name: Kim Schmelzer

Contact Title: Quality Manager

Correspondent Firm:

Phone: 952-470-0866 **Email:** (b)(6)

Received Date: October 9, 2015

Due Date: December 8, 2015

Reg #: 882.1330 **Reg Name:** Depth Electrode

Class: II **Product Code(s):** GZL

Predicate Devices:

Submission #	Pro Code	Device Trade Name	Owner
K802152	GZL	PMT Depthalon Depth #2102	Progress Mankind Technology
K041604	GZL	Macro-micro Depth Electrode	Ad-tech Medical Instrument Corp.

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

Records processed under FOIA Request 2024-2207; Released by CDRH on 11-13-2024

(b)(5)

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

Records processed under FOIA Request 2024-2207; Released by CDRH on 11-13-2024

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

Records processed under FOIA Request 2015-4107; Released by CDRH on 11-13-2024

Contains Nonbinding Recommendations

Print Form

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) #: K151790 Date Received by DCC: Jul 24, 2015

Lead Reviewer: Stacie Gutowski

Branch: NSDB Division: DNPMD Center/Office: CDRH/ODE

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 the element will be assessed during the substantive review.

Preliminary Questions Answers in the shaded blocks indicate consultations 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."		
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."		
Comments?		
3) If a Request for Designation 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: 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 is no, mark "No." If there was no RFD, skip this question.		(b)(4)
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."		
Comments?		

Records processed under FOIA Request 2024-2207; Released by CDRH on 11-13-2024

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.

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

(b)(4)

Comments?

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.
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.

Records processed under FOIA Request 2024-2267 Released by CDRH on 11-13-2024

Organizational Elements

Failure to include these items alone generally should not result in an RTA designation.

	Yes	No
1) Submission contains a Table of Contents	(b)(4)	
2) Each section is labeled (e.g., headings or tabs designating Device Description section, Labeling section, etc.)		
3) All pages of the submission are numbered.		
4) Type of 510(k) is identified (i.e., traditional, abbreviated, or special)		
Comments?		

Received per FOIA Request 2022-2597, Released by CDRH on 11-13-2024

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. An applicant may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criteria is considered Present (Yes). An assessment of the rationale will be considered during the review of the submission.	Yes	No	N/A	Comment
A. Administrative				
1) All content used to support the submission is written in English (including translations of test reports, literature articles, etc.)				
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				
b) Device common name				
c) Device class and panel or Classification regulation or Statement that device has not been classified with rationale for that conclusion				
3) Submission contains Indications for Use Statement with Rx and/or OTC designation (see also 21 CFR 801.109).				
4) Submission contains 510(k) Summary or 510(k) Statement				
a) Summary contains all elements per 21 CFR 807.92 *(See also* 510(k) Summary Checklist*)*				
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.				
Comments?				
6) Submission contains Class III Summary and Certification. *See recommended* content.				
7) Submission contains clinical data				
8) If submission references use of a national or international standard as part of demonstration of substantial equivalence, submission contains Standards Data Report for 510(k)s (Form 3654) or includes detailed information about how and the extent to which the standard has been followed.				

(b)(4)

(b)(4)

(b)(4)

(b)(4)

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

Received per FOIA Request 2024-5197, Released by CDRH on 11-19-2024

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. An applicant may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criteria is considered Present (Yes). An assessment of the rationale will be considered during the review of the submission.	Yes	No	N/A	Comment
Comments?	(b)(4)			
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.	(b)(4)			
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. 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." Once finalized, this guidance will represent the Agency's current thinking on this topic.				
Comments?	(b)(4)			

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.	(b)(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.				
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.				
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.				
c) A list and description of each device for which clearance is requested.				
Comments?	(b)(4)			

Received per Section 520(g)(7) Request by CDRH on 11-13-2024

Elements of a Complete Submission (RTA Items)
(21 CFR 807.87 unless otherwise indicated)

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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. An applicant may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criteria is considered Present (Yes). An assessment of the rationale will be considered during the review of the submission.	Yes	No	N/A	Comment
(b)(4)				
12) Submission contains representative engineering drawing(s), schematics, illustrations and/or figures of the device that are clear, legible, labeled, and include dimensions.				
13) If device is 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.				
b) Submission includes a description (as detailed in item 11(a) and (b) and 12 above) of each component or accessory.				
c) A 510(k) number is provided for each component or accessory that received a prior 510(k) clearance.				
Comments? (b)(4)				

C. Substantial Equivalence Discussion

14) Submitter has identified a predicate device.				
a) Predicate's 510(k) number, trade name, and model number (if applicable) provided. For predicates that are preamendments devices, information is provided to document preamendments status. *Information regarding* documenting preamendment status *is available online.*				
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.				
15) Submission includes a comparison of the following for the predicate(s) and subject device				
a) Indications for Use				
b) Technology, including features, materials, and principles of operation				
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))				
Comments? (b)(4)				

(b)(4)

(b)(4)

Received per Section 520(g)(2)(B) of the FD&C Act by CDRH on 11-13-2024

Elements of a Complete Submission (RTA Items)
(21 CFR 807.87 unless otherwise indicated)

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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. An applicant may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criteria is considered Present (Yes). An assessment of the rationale will be considered during the review of the submission.	Yes	No	N/A	Comment
(b)(4)				

D. Proposed Labeling (see also 21 CFR part 801)

If *in vitro* diagnostic (IVD) device, criteria 17 & 19 may be omitted.

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.	(b)(4)
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).	
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) AND - includes directions for layperson (see 21 CFR 801.5) OR submission states that device qualifies for exemption per 21 CFR 801 Subpart D	
Comments?	(b)(4)
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]	(b)(4)
19) General labeling provisions	
a) Labeling includes name and place of business of the manufacturer, packer, or distributor (21 CFR 801.1).	
b) Labeling includes device common or usual name. (21 CFR 801.61)	
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.	
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.	
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.	
21) If the device is an in vitro diagnostic device, provided labeling includes all applicable information required per 21 CFR 809.10.	

Received per FOIA Request 2022-2537, Released by CDRH on 11-13-2024

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. An applicant may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criteria is considered Present (Yes). An assessment of the rationale will be considered during the review of the submission.	Yes	No	N/A	Comment
E. Sterilization				
If IVD device and sterilization is not applicable, select "N/A" and criteria below will be omitted from checklist.				
Submission states that the device and/or accessories are: (one of the below must be checked)				
X provided sterile				
X provided non-sterile but sterilized by the end user				
non-sterile when used				
Information regarding the sterility status of the device is not provided.				
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.				
22) Assessment of the need for sterilization information				
a) Identification of device, and/or accessories, and/or components that are provided sterile.				
b) Identification of device, and/or accessories, and/or components that are end user sterilized.				
c) Identification of device, and/or accessories, and/or components that are reusable and cleaning /disinfection instructions are provided.				
Comments?	(b)(4)			
23) If the device, and/or accessory, and/or a component is provided sterile:				
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 levels of sterilant residuals remaining on the device and sterilant residual limits.				
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) is stated.				
24) If the device, and/or accessory, and/or a component is end user sterilized:				
a) Sterilization method is stated for each component (including parameters such as dry time for steam sterilization, radiation dose, etc.).				

(b)(4)

(b)(4)

(b)(4)

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. An applicant may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criteria is considered Present (Yes). An assessment of the rationale will be considered during the review of the submission.	Yes	No	N/A	Comment
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) Submission includes description of packaging and packaging contents (e.g., if multiple devices are included within the same package, Tyvek packaging, etc.).				
d) Submission includes sterilization instructions for end user.				
Comments?	(b)(4)			
25)				
a) If there are requirements regarding sterility, such as special 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.				
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.				
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.				
F. Shelf Life				
26) Proposed shelf life/expiration date stated				
27) For sterile device, submission includes summary of methods used to establish that device will remain sterile through the proposed shelf life or a rationale for why testing to establish shelf life is not applicable.				
Comments?	(b)(4)			
28) Submission includes summary of methods used to establish that device performance is not adversely affected by aging or includes a rationale for why the storage conditions are not expected to affect device safety or effectiveness.				
G. Biocompatibility				
If IVD device, select "N/A" and the below criteria will be omitted from checklist.				
Submission states that there: (one of the below must be checked)				
are direct or indirect (e.g., through fluid infusion) patient contacting components.	X			

(b)(4)

(b)(4)

(b)(4)

Received: [illegible] 2024

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. An applicant may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criteria is considered Present (Yes). An assessment of the rationale will be considered during the review of the submission.	Yes	No	N/A	Comment
are no direct or indirect (e.g., through fluid infusion) patient-contacting components.				
Information regarding the patient contact status of the device is not provided.				
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.				
29) Submission includes list of patient-contacting device components and associated materials of construction, including identification of color additives, if present				
Comments? (b)(4)				
30) Submission identifies contact classification (e.g., surface-contacting, less then 24 hour duration, etc.)				
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).				
Comments? (b)(4)				

(b)(4)

H. Software

Submission states that the device: (one of the below must be checked)

- does contain software/firmware.
- × does not contain software/firmware.
- Information regarding whether the device contains software is not provided.

This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.

(b)(4)

I. EMC and Electrical Safety

Submission states that the device: (one of the below must be checked)

- does require EMC and Electrical Safety evaluation.
- × does not require EMC and Electrical Safety evaluation.
- Information regarding whether the device requires EMC and Electrical Safety evaluation is not provided.

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

Received per Section 520(c)(2) of the FD&C Act by CDRH on 11-13-2024

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. An applicant may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criteria is considered Present (Yes). An assessment of the rationale will be considered during the review of the submission.	Yes	No	N/A	Comment
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.				
J. Performance Data - General If IVD device, select "N/A" and the below criteria will be omitted from checklist. Performance data criteria relating to IVD devices will be addressed in Section K.				
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.				
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.				
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 approach.				
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.				
38) If literature is referenced in the submission, submission includes:				
39) For each completed nonclinical (i.e., animal) study conducted				

(b)(4)

K. Performance Characteristics - In Vitro Diagnostic Devices Only **(Also see 21 CFR 809.10(b)(12))**	
Submission states that the device: (one of the below must be checked)	
is an in vitro diagnostic device.	
× is not an in vitro diagnostic device.	

Records processed under FOIA Request 2024-2207; Released by CDRH on 11-13-2024

Decision: (b)(4)

If Accept, notify applicant.

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

Digital Signature Concurrence Table

Reviewer Sign-Off	Stacie M. Gutowski -S 2015.07.30 09:18:20 -04'00'
Branch Chief Sign-Off (digital signature optional)*	Timothy A. Marjenin -S 2015.07.31 11:34:49 -04'00'
Division Sign-Off (digital signature optional)*	Timothy A. Marjenin -S 2015.07.31 11:35:07 -04'00'

* Branch and Division review of checklist and concurrence with decision required. Branch and Division digital signature optional.

Records processed under FOIA Request 2024-2207; Released by CDRH on 11-13-2024

ORIGINAL

PMT CORPORATION

Document type: TECHNICAL PROTOCOL	Document No. (b)(4)	Page 1 of 5
Document title: (b)(4)	Effective Date 5/15/2015	Current Rev. (b)(4)

(b)(4)

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

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Records processed under FOIA Request 2024-2207; Released by CDRH on 11-13-2024

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Records processed under FOIA Request 2024-2207; Released by CDRH on 11-13-2024

Department of Health & Human Services **Food and Drug Administration**

K151790
(Traditional 510k)

Hyung-yul Lee -S
2015.11.29 09:37:14
-05'00'

Date: November 30, 2015

To: Stacie Gutowski, PhD
Team Leader
DNPMD/NSDB

From: Hyung Lee, PhD
Sterility Reviewer
DNPMD/NSDB

Cc: The Record

Device Name: (b)(5)

Sponsor: PMT, Corp.

Re: Clearance for Depthalon® Depth Electrodes

(b)(5)

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

Records processed under FOIA Request 2024-2207; Released by CDRH on 11-13-2024

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From: Kim Schmelzer [mailto (b)(6)
Sent: Wednesday, June 29, 2016 12:15 PM
To: Gutowski, Stacie
Cc: (b)(6)
Subject: Interactive Review for K151790

Stacie,

Below is (b)(4) from your email dated 6/27/2016.

(b)(4)

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

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(b)(4)

I hope this answers your question. Please let me know if you have any further questions.

Thank you,
Kim Schmelzer | Quality Manager
PMT Corporation | Permark
1500 Park Road Chanhassen MN 55317 USA
D: +952.470.0866 | F: +952.470.0865
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Document type: TECHNICAL REPORT	Document No. (b)(4)	Page 1 of 10
Document title: (b)(4)	Effective Date 4/30/2011	Current Rev. (b)(4)

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Hello Ms. Schmelzer,
We are in the process of reviewing the response for K151790 (b)(4)

(b)(4)

(b)(4) Please be sure to cc the document email box above (k151790@docs.fda.gov). This will help us move forward with the review.

Sincerely,
Stacie Gutowski, Ph.D.
Biomedical Engineer
ODE/DNPMD/NSDB
WO 66, Rm 2656
10903 New Hampshire Avenue
Silver Spring, MD 20993
(240) 402-6032
Stacie.Gutowski@fda.hhs.gov

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(b)(4)

PMT CORPORATION

Platinum Depthalon Depth Electrode

(b)(4)

(b)(4) Evaluation

(b)(4)

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Hi Stacie - We can do a conference call tomorrow. Is there a dial in # for the call?

(b)(4)

Thanks for your help on this submittal.

- Ben

Benjamin Osa

Neurosurgery Engineering Manager

PMT Corporation

1500 Park Road

Chanhassen, MN 55317

Email: <mailto:(b)(6)

(P) 952-470-0866

(F) 952-470-0865

From: Gutowski, Stacie [mailto:Stacie.Gutowski@fda.hhs.gov]

Sent: Wednesday, June 15, 2016 3:58 PM

To: Ben Osa

Cc: k151790@docs.fda.gov; (b)(6)

Subject: RE: FDA requesting teleconference with your team

Hello Ben,

(b)(4)

Stacie Gutowski, Ph.D.

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

Records processed under FOIA Request 2024-2207; Released by CDRH on 11-13-2024

Biomedical Engineer

ODE/DNPMD/NSDB

WO 66, Rm 2656

10903 New Hampshire Avenue

Silver Spring, MD 20993

(240) 402-6032

Stacie.Gutowski@fda.hhs.gov

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From: Ben Osa [mailto: (b)(6)

Sent: Wednesday, June 15, 2016 4:52 PM

To: Gutowski, Stacie

Cc: k151790@docs.fda.gov; (b)(6)

Subject: FDA requesting teleconference with your team

Hi Stacie - (b)(6)

(b)(6)

Is there a way we can do a teleconference on that date or a day soon afterwards?

Please let me know.

Thanks,

- Ben

Benjamin Osa

Neurosurgery Engineering Manager

PMT Corporation

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

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1500 Park Road

Chanhassen, MN 55317

Email: (b)(6)

(P) 952-470-0866

(F) 952-470-0865

From: Gutowski, Stacie [mailto:Stacie.Gutowski@fda.hhs.gov]
Sent: Wednesday, June 15, 2016 1:47 PM
To: Kim Schmelzer
Cc: k151790@docs.fda.gov
Subject: FDA requesting teleconference with your team

Hello Kim,

(b)(4)

Sincerely,

Stacie Gutowski, Ph.D.

Biomedical Engineer

ODE/DNPMD/NSDB

WO 66, Rm 2656
10903 New Hampshire Avenue
Silver Spring, MD 20993
(240) 402-6032

Stacie.Gutowski@fda.hhs.gov

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SUBJECT: (b)(4)

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From: LaGuerre Jones, Gabrielle * [Gabrielle.LaGuerreJones@fda.hhs.gov]
Sent: 10/8/2015 2:41:23 PM
To: (b)(6)
CC: DCCLetters [DCCLetters@fda.hhs.gov]
Subject: K151790/S001-ECOPY HOLD LETTER W/ ATTACHMENT
Attachments: K151790-S001.pdf

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DEPARTMENT OF HEALTH AND HUMAN SERVICES **Public Health Service**

eCopy Hold Letter

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

10/08/2015

KIM SCHMELZER
QUALITY MANAGER
PMT CORPORATION
1500 PARK RD
CHANHASSEN, MN 55317
United States

Dear KIM SCHMELZER:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has received your submission. This submission has been assigned the unique document control number below. Failure to reference this assigned number in future correspondence may result in processing delays.

Submission Number: K151790/S001
Received: 10/08/2015
Applicant: PMT CORPORATION
Device: (b)(4)

The Federal Food, Drug, and Cosmetic Act (the Act), as amended by section 1136 of the Food and Drug Administration Safety and Innovation Act (FDASIA), authorizes FDA to require an electronic copy (eCopy) for certain types of submissions. **You have received this letter because you have either not provided an eCopy or you provided an eCopy that failed the loading process because it did not meet the technical standards.** If you provided an eCopy that failed the loading process, then please see the attached document that identifies all reasons for the failure that need to be addressed. To understand the reasons for your eCopy failure, please refer to the eCopy guidance document, "eCopy Program for Medical Device Submissions" at http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM313794.pdf.

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When your Replacement eCopy has been received and been verified as a valid eCopy, review of this submission will start as of that date.

If you have any questions concerning this letter, please contact the eCopy Program Coordinators at (240) 402-3717 or at CDRH-eCopyinfo@fda.hhs.gov.

Sincerely yours,

Center for Devices and Radiological Health

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Attachment

Attachment for Submission Number(s):	
K151790/S001	

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PMT CORPORATION

Platinum Depthalon Depth Electrode
Lot No.: (b)(4)

(b)(4)

May 20, 2014

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Questions? Contact FDA/CDRH/CCE/IDT CDRH-FOIASTATUS@fda.hhs.gov or 301-796-8118

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From: Kim Schmelzer [mailto:(b)(6)

Sent: Thursday, June 23, 2016 2:31 PM

To: Gutowski, Stacie

Cc: (b)(6)

Subject: Follow-up deficiency information for K151790

June 23, 2016

U.S. Food and Drug Administration

Center for Devices and Radiological Health

Document Control Center - WO66-G609

10903 New Hampshire Avenue

Silver Spring, MD 20993-0002

RE: K157190/S002

Device Name: PMT Platinum Depthalon(r) Depth Electrodes

Stacie Gutowski, Ph.D.,

The attached information located in this email is in response to your email received at PMT Corporation on Monday June 20, 2016 regarding the premarket 510(k) notification for PMT(r) Platinum Depthalon(r) Depth Electrodes. (b)(4) (b)(4) Should you have any questions please contact me.

Thank you,

Kim Schmelzer | Quality Manager

PMT Corporation | Permark

1500 Park Road Chanhassen MN 55317 USA

D: +952.470.0866 | F: +952.470.0865

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1500 Park Road • Chanhassen, MN 55317 USA • Phone (952) 470-0866 • Fax (952) 470-0865 • www.pmtcorp.com

PMT Corporation
510(k) Statement

510(k) Number: K151790

I certify that, in my capacity as Quality Manager of PMT Corporation, I will make available all information included in this premarket notification on safety and effectiveness within 30 days of request by any person if the device described in the premarket notification submission is determined to be substantially equivalent. The information I agree to make available will be a duplicate of the premarket notification submission, including any adverse safety and effectiveness information, but excluding all patient identifiers, and trade secret and confidential commercial information, as defined in 21 CFR 20.61.

(b)(6)

Date: 9/30/15

Kim Schmelzer
Quality Manager
PMT Corporation

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

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Document type: TECHNICAL PROTOCOL	Document No. (b)(4)	Page 1 of 4
Document title: (b)(4) Validation Protocol	Effective Date 7/24/09	Current Rev. (b)(4)

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1500 Park Road - P.O. Box 610
Chanhassen, MN 55317

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Description of product packaging of the Depthalon Depth Electrodes

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From: Gutowski, Stacie

Sent: Friday, July 31, 2015 2:01 PM

To: 'Kim Schmelzer'

Subject: RE: K151790 is on Hold Pending Your Response

Hello Kim,

(b)(4)

Please let me know if this is still unclear, or if you have any additional questions.

Sincerely,

Stacie Gutowski, Ph.D.

Biomedical Engineer

ODE/DNPMD/NSDB

White Oak Building #66, Room 1436

10903 New Hampshire Avenue

Silver Spring, MD 20993

(240) 402-6032

Stacie.Gutowski@fda.hhs.gov<mailto:Stacie.Gutowski@fda.hhs.gov>

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From: Kim Schmelzer [mailto:(b)(6)

Sent: Friday, July 31, 2015 1:06 PM

To: Gutowski, Stacie

Subject: RE: K151790 is on Hold Pending Your Response

Stacie,

Thank you for your prompt response.

(b)(4)

Kim Schmelzer | Quality Manager

PMT Corporation | Permark

1500 Park Road Chanhassen MN 55317 USA

D: +952.470.0866 | F: +952.470.0865

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From: Gutowski, Stacie [mailto:Stacie.Gutowski@fda.hhs.gov]

Sent: Friday, July 31, 2015 11:55 AM

To: Kim Schmelzer

Subject: RE: K151790 is on Hold Pending Your Response

Hello Kim,

Thank you for your email, I'm happy to answer your questions.

(b)(4)

Please don't hesitate to contact me if you have any additional questions.

Sincerely,

Stacie Gutowski, Ph.D.

Biomedical Engineer

ODE/DNPMD/NSDB

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(240) 402-6032

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From: Kim Schmelzer [mailto:(b)(6)

Sent: Friday, July 31, 2015 12:25 PM

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To: Gutowski, Stacie

Subject: RE: K151790 is on Hold Pending Your Response

Stacie,

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Kim Schmelzer | Quality Manager

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From: Stacie Gutowski [mailto:stacie.gutowski@fda.hhs.gov]

Sent: Friday, July 31, 2015 10:36 AM

To: (b)(6)

Cc: Stacie Gutowski

Subject: K151790 is on Hold Pending Your Response

July 31, 2015 Acceptance Review Notification - Refuse To Accept (RTA)

We have completed the administrative acceptance review of your premarket notification (510(k)) submission K151790. Our review indicates that your 510(k) submission does not meet the criteria established for administrative completeness. Thus, we regret to inform you that we are unable to conduct a substantive review of your submission at this time and are placing it on RTA hold.

Please submit two copies of your response (1 eCopy and 1 paper copy), referencing the 510(k) number K151790, addressing the elements identified as missing or inconsistent in the attached checklist to:

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

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U.S. Food and Drug Administration

Center for Devices and Radiological Heath

Document Control Center - WO66-G609

10903 New Hampshire Avenue

Silver Spring, MD 20993-0002

FDA will permit your 510(k) submission to remain on hold for a maximum of 180 days from the date of this email. If you do not correct the missing or inconsistent elements identified in the checklist within 180 days, we will consider this 510(k) submission to be withdrawn, and we will delete it from our review system.

Upon receipt of the requested information, FDA will conduct another administrative review of your 510(k) submission.

Should you have questions about this email, you may contact Stacie Gutowski, the lead reviewer assigned to your 510(k) submission.

For additional information regarding the Refuse to Accept Policy for 510(k)s<http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM315014.pdf> please refer to the guidance document available at http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM315014.pdf.

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From: Gutowski, Stacie

Sent: Friday, July 31, 2015 12:55 PM

To: 'Kim Schmelzer'

Subject: RE: K151790 is on Hold Pending Your Response

Hello Kim,

Thank you for your email, I'm happy to answer your questions.

(b)(4)

Please don't hesitate to contact me if you have any additional questions.

Sincerely,

Stacie Gutowski, Ph.D.

Biomedical Engineer

ODE/DNPMD/NSDB

White Oak Building #66, Room 1436

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(240) 402-6032

Stacie.Gutowski@fda.hhs.gov<mailto:Stacie.Gutowski@fda.hhs.gov>

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Sent: Friday, July 31, 2015 12:25 PM

To: Gutowski, Stacie

Subject: RE: K151790 is on Hold Pending Your Response

Stacie,

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From: Stacie Gutowski [mailto:stacie.gutowski@fda.hhs.gov]

Sent: Friday, July 31, 2015 10:36 AM

To: (b)(6)

Cc: Stacie Gutowski

Subject: K151790 is on Hold Pending Your Response

July 31, 2015 Acceptance Review Notification - Refuse To Accept (RTA)

We have completed the administrative acceptance review of your premarket notification (510(k)) submission K151790. Our review indicates that your 510(k) submission does not meet the criteria established for administrative completeness. Thus, we regret to inform you that we are unable to conduct a substantive review of your submission at this time and are placing it on RTA hold.

Please submit two copies of your response (1 eCopy and 1 paper copy), referencing the 510(k) number K151790, addressing the elements identified as missing or inconsistent in the attached checklist to:

U.S. Food and Drug Administration

Center for Devices and Radiological Heath

Document Control Center - WO66-G609

10903 New Hampshire Avenue

Silver Spring, MD 20993-0002

FDA will permit your 510(k) submission to remain on hold for a maximum of 180 days from the date of this email. If you do not correct the missing or inconsistent elements

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identified in the checklist within 180 days, we will consider this 510(k) submission to be withdrawn, and we will delete it from our review system.

Upon receipt of the requested information, FDA will conduct another administrative review of your 510(k) submission.

Should you have questions about this email, you may contact Stacie Gutowski, the lead reviewer assigned to your 510(k) submission.

For additional information regarding the Refuse to Accept Policy for 510(k)s<http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM315014.pdf> please refer to the guidance document available at http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM315014.pdf.

*** This is a system-generated email notification ***

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(b)(4) VALIDATION REPORT

SPONSOR: PMT CORPORATION

TEST MEDICAL DEVICES: (b)(4)

TITLE: (b)(4)

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DEPARTMENT OF HEALTH AND HUMAN SERVICES **M E M O R A N D U M**

Food and Drug Administration
Office of Device Evaluation

510(k) SE Package Correction Memo

K151790

Date: July 15, 2016
To: The Record
From: Stacie Gutowski

Office: ODE
Division: DNPMD

Sponsor: PMT Corporation
Device Name: PMT Platinum Depthalon Depth Electrodes
Contact: Kim Schmelzer
Quality Manager
1500 Park Road
Chanhassen, MN 55317
Phone: (952)470-0866
Fax:
Email: (b)(6)

Stacie M. Gutowski -S
2016.07.15 10:54:43
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(b)(5)

(b)(5)

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From: Kim Schmelzer [mailto:(b)(6)
Sent: Wednesday, June 22, 2016 5:15 PM
To: Gutowski, Stacie
Cc: (b)(6)
Subject: Response to Questions 2a and 2b

Stacie,

Please see PMT's response to your questions below. Contact me with any questions.

(b)(4)

Thank you,
Kim Schmelzer | Quality Manager
PMT Corporation | Permark
1500 Park Road Chanhassen MN 55317 USA
D: +952.470.0866 | F: +952.470.0865
www.pmtcorp.com | www.permark.com

Description: pmt_logo

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Hello Kim,

(b)(4) Can we setup a teleconference meeting with you and your team tomorrow afternoon at 2pm (eastern time)? Please let me know if you are available.

Sincerely,

Stacie Gutowski, Ph.D.

Biomedical Engineer

ODE/DNPMD/NSDB

WO 66, Rm 2656

10903 New Hampshire Avenue

Silver Spring, MD 20993

(240) 402-6032

Stacie.Gutowski@fda.hhs.gov<mailto:Stacie.Gutowski@fda.hhs.gov>

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Dear Kim,

The team is actively reviewing your submission supplement for K151790 and (b)(4) (b)(4) Please note that we have entered the "interactive review" portion of our timeline, which means that you should respond (b)(4) via direct email to me, and be sure to copy the document mailbox (k151790@docs.fda.gov) which is also cc'd on this email. You do not need to submit the response to document control at this time. In order to move forward with our review we need to have a response to all items below by 8am on Friday June 24, 2016. Please do not hesitate to call or email with any questions.

(b)(4)

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

Records processed under FOIA Request 2024-2207; Released by CDRH on 11-13-2024

(b)(4)

Stacie Gutowski, Ph.D.
Biomedical Engineer
ODE/DNPMD/NSDB
WO 66, Rm 2656
10903 New Hampshire Avenue
Silver Spring, MD 20993
(240) 402-6032
Stacie.Gutowski@fda.hhs.gov

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(b)(4)

SUBJECT: (b)(4)

(b)(4)

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(b)(4)

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(b)(4)

Stacie Gutowski, Ph.D.

Biomedical Engineer

ODE/DNPMD/NSDB

WO 66, Rm 2656

10903 New Hampshire Avenue

Silver Spring, MD 20993

(240) 402-6032

Stacie.Gutowski@fda.hhs.gov<mailto:Stacie.Gutowski@fda.hhs.gov>

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Hello Ben,

Thank you for understanding. The call-in information is below. We look forward to speaking with you at 2pm (eastern) on June 16.

(b)(4)

Stacie Gutowski, Ph.D.

Biomedical Engineer

ODE/DNPMD/NSDB

WO 66, Rm 2656

10903 New Hampshire Avenue

Silver Spring, MD 20993

(240) 402-6032

Stacie.Gutowski@fda.hhs.gov<mailto:Stacie.Gutowski@fda.hhs.gov>

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From: Ben Osa [mailto:(b)(6)

Sent: Wednesday, June 15, 2016 5:29 PM

To: Gutowski, Stacie

Cc: k151790@docs.fda.gov; (b)(6)

Subject: RE: FDA requesting teleconference with your team

Hi Stacie - We can do a conference call tomorrow. Is there a dial in # for the call?

(b)(4)

Thanks for your help on this submittal.

- Ben

Benjamin Osa

Neurosurgery Engineering Manager

PMT Corporation

1500 Park Road

Chanhassen, MN 55317

Email: (b)(6) <mailto (b)(6)

(P) 952-470-0866

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

Records processed under FOIA Request 2024-2207; Released by CDRH on 11-13-2024

(F) 952-470-0865

From: Gutowski, Stacie [mailto:Stacie.Gutowski@fda.hhs.gov]

Sent: Wednesday, June 15, 2016 3:58 PM

To: Ben Osa

Cc: k151790@docs.fda.gov<mailto:k151790@docs.fda.gov>;
(b)(6) <mailto: (b)(6)

Subject: RE: FDA requesting teleconference with your team

Hello Ben,

(b)(4)

Stacie Gutowski, Ph.D.

Biomedical Engineer

ODE/DNPMD/NSDB

WO 66, Rm 2656

10903 New Hampshire Avenue

Silver Spring, MD 20993

(240) 402-6032

Stacie.Gutowski@fda.hhs.gov<mailto:Stacie.Gutowski@fda.hhs.gov>

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https://www.research.net/s/cdrhcustomerservice?O=400&D=460&B=462&E=&S=E

From: Ben Osa [mailto: (b)(6)

Sent: Wednesday, June 15, 2016 4:52 PM

To: Gutowski, Stacie

Cc: k151790@docs.fda.gov<mailto:k151790@docs.fda.gov>;
(b)(6) <mailto: (b)(6) >

Subject: FDA requesting teleconference with your team

Hi Stacie - (b)(6)
(b)(6)

Is there a way we can do a teleconference on that date or a day soon afterwards?

Please let me know.

Thanks,

- Ben

Benjamin Osa

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

Records processed under FOIA Request 2024-2207; Released by CDRH on 11-13-2024

Neurosurgery Engineering Manager

PMT Corporation

1500 Park Road

Chanhassen, MN 55317

Email: (b)(6) <mailto: (b)(6) >

(P) 952-470-0866

(F) 952-470-0865

From: Gutowski, Stacie [mailto:Stacie.Gutowski@fda.hhs.gov]

Sent: Wednesday, June 15, 2016 1:47 PM

To: Kim Schmelzer

Cc: k151790@docs.fda.gov<mailto:k151790@docs.fda.gov>

Subject: FDA requesting teleconference with your team

Hello Kim,

(b)(4) Can we setup a teleconference meeting with you and your team tomorrow afternoon at 2pm (eastern time)? Please let me know if you are available.

Sincerely,

Stacie Gutowski, Ph.D.

Biomedical Engineer

ODE/DNPMD/NSDB

WO 66, Rm 2656

10903 New Hampshire Avenue

Silver Spring, MD 20993

(240) 402-6032

Stacie.Gutowski@fda.hhs.gov<mailto:Stacie.Gutowski@fda.hhs.gov>

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DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service

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

July 29, 2016

PMT Corporation
Kim Schmelzer
Quality Manager
1500 Park Road
Chanhassen, MN 55317

Re: K151790
Trade/Device Name: PMT Platinum Depthalon Depth Electrodes
Regulation Number: 21 CFR 882.1330
Regulation Name: Depth Electrode
Regulatory Class: Class II
Product Code: GZL
Dated: June 9, 2016
Received: October 9, 2015

Dear Kim Schmelzer:

This letter corrects our substantially equivalent letter of July 14, 2016.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

Records processed under FOIA Request 2024-2207; Released by CDRH on 11-13-2024

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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

Sincerely,

William J. Heetderks -A

Digitally signed by William J. Heetderks -A
DN: c=US, o=U.S. Government, ou=HHS, ou=NIH, ou=People, 0.9.2342.19200300.100.1.1=0010149848, cn=William J. Heetderks -A
Date: 2016.07.29 11:32:59 -04'00'

for Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

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

Records processed under FOIA Request 2024-2207; Released by CDRH on 11-13-2024

DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
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Sincerely,

William J. Heetderks -A

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DN: c=US, o=U.S. Government, ou=HHS, ou=NIH, ou=People, 0.9.2342.19200300.100.1.1=0010149848, cn=William J. Heetderks -A
Date: 2016.07.15 11:58:37 -04'00'

for Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

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PMT® Corporation
1500 PARK ROAD · CHANHASSEN, MN 55317 USA · PHONE (952) 470-0866 · 1-800-MANKIND · FAX (952) 470-0865

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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)

PMT CORP.
1500 PARK RD.
P.O. BOX 610
CHANHASSEN
MN 55317
US

1.1 EMPLOYER IDENTIFICATION NUMBER (EIN)
*****3591

2. CONTACT NAME
Al Iversen
2.1 E-MAIL ADDRESS
(b)(6)
2.2 TELEPHONE NUMBER (include Area code)
952-470-0866
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:
[X] Premarket notification(510(k)); except for third party
[ ] 513(g) Request for Information
[ ] Biologics License Application (BLA)
[ ] Premarket Approval Application (PMA)
[ ] Modular PMA
[ ] Product Development Protocol (PDP)
[ ] Premarket Report (PMR)
[ ] 30-Day Notice

3.1 Select a center
[X] CDRH
[ ] CBER

3.2 Select one of the types below
[X] Original Application

Supplement Types:
[ ] Efficacy (BLA)
[ ] Panel Track (PMA, PMR, PDP)
[ ] 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.

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

Records processed under FOIA Request 2024-2207; Released by CDRH on 11-13-2024

[ ] 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
[ ] 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) 04-Jun-2015

Form FDA 3601 (05/13)

"Close Window" Print Cover sheet

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PMT®

1500 Park Road • Chanhassen, MN 55317 USA • Phone (952) 470-0866 • Fax (952) 470-0865 • www.pmtcorp.com

Indications for Use Statement

510(k) Number (if known): K151790

Device Name

PMT® Platinum Depthalon® Depth Electrodes

Indications for Use

The Platinum Depthalon® Depth Electrodes are intended for temporary (<30 day) use with recording, monitoring, and stimulation equipment for the recording, monitoring and stimulation of electrical signals in the subsurface of the brain.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use __X___ OR Over the Counter Use_____
(Per 21 CFR 801.109

(Optimal Format 1-2-96)

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Hello Ben,

(b)(4)

Stacie Gutowski, Ph.D.
Biomedical Engineer
ODE/DNPMD/NSDB
WO 66, Rm 2656
10903 New Hampshire Avenue
Silver Spring, MD 20993
(240) 402-6032
Stacie.Gutowski@fda.hhs.gov

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From: Ben Osa [mailto:(b)(6)
Sent: Wednesday, June 15, 2016 4:52 PM
To: Gutowski, Stacie
Cc: k151790@docs.fda.gov; (b)(6)
Subject: FDA requesting teleconference with your team

Hi Stacie – (b)(6)

Is there a way we can do a teleconference on that date or a day soon afterwards?

Please let me know.

Thanks,

- Ben

Benjamin Osa
Neurosurgery Engineering Manager
PMT Corporation
1500 Park Road
Chanhassen, MN 55317
Email: (b)(6)
(P) 952-470-0866
(F) 952-470-0865

From: Gutowski, Stacie [mailto:Stacie.Gutowski@fda.hhs.gov]
Sent: Wednesday, June 15, 2016 1:47 PM
To: Kim Schmelzer
Cc: k151790@docs.fda.gov
Subject: FDA requesting teleconference with your team

Hello Kim,

(b)(4) Can we setup a teleconference meeting with you and your team tomorrow afternoon at 2pm (eastern time)? Please let me know if you are available.

Sincerely,
Stacie Gutowski, Ph.D.
Biomedical Engineer
ODE/DNPMD/NSDB
WO 66, Rm 2656
10903 New Hampshire Avenue
Silver Spring, MD 20993
(240) 402-6032
Stacie.Gutowski@fda.hhs.gov

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Dear applicant,

Please see corrected SE letter attached.

Please feel free to contact me if you have any questions.

Thank you,

Edwena

Edwena R. Jones

Premarket Notification (510(k)) Staff

Office of Device Evaluation

Center for Devices and Radiological Health

Food and Drug Administration

edwena.jones@fda.hhs.gov

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Department of Health & Human Services **Food and Drug Administration**

K151790
(Traditional 510k)

Date: November 30, 2015

To: Stacie Gutowski, PhD
Team Leader
DNPMD/NSDB

From: Hyung Lee, PhD
Sterility Reviewer
DNPMD/NSDB

Cc: The Record

Device Name: (b)(5)

Sponsor: PMT, Corp.

Re: Clearance for Depthalon® Depth Electrodes

(b)(5)

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DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service

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

July 29, 2016

PMT Corporation
Kim Schmelzer
Quality Manager
1500 Park Road
Chanhassen, MN 55317

Re: K151790
Trade/Device Name: PMT Platinum Depthalon Depth Electrodes
Regulation Number: 21 CFR 882.1330
Regulation Name: Depth Electrode
Regulatory Class: Class II
Product Code: GZL
Dated: June 9, 2016
Received: October 9, 2015

Dear Kim Schmelzer:

This letter corrects our substantially equivalent letter of July 14, 2016.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

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CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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

Sincerely,

William J. Heetderks -A

Digitally signed by William J. Heetderks -A
DN: c=US, o=U.S. Government, ou=HHS, ou=NIH, ou=People, 0.9.2342.19200300.100.1.1=0010149848, cn=William J. Heetderks -A
Date: 2016.07.29 11:32:59 -04'00'

for Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

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(b)(4)

PMT CORPORATION

Platinum Depthalon Depth Electrode

(b)(4)

(b)(4) Test

(b)(4)

April 22, 2014

(b)(4)

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Hi Stacie - (b)(6)

Is there a way we can do a teleconference on that date or a day soon afterwards?

Please let me know.

Thanks,

- Ben

Benjamin Osa
Neurosurgery Engineering Manager
PMT Corporation
1500 Park Road
Chanhassen, MN 55317
Email: (b)(6)
(P) 952-470-0866
(F) 952-470-0865

From: Gutowski, Stacie [mailto:Stacie.Gutowski@fda.hhs.gov]
Sent: Wednesday, June 15, 2016 1:47 PM
To: Kim Schmelzer
Cc: k151790@docs.fda.gov
Subject: FDA requesting teleconference with your team

Hello Kim,

(b)(4) Can we setup a teleconference meeting with you and your team tomorrow afternoon at 2pm (eastern time)? Please let me know if you are available.

Sincerely,
Stacie Gutowski, Ph.D.
Biomedical Engineer
ODE/DNPMD/NSDB
WO 66, Rm 2656
10903 New Hampshire Avenue
Silver Spring, MD 20993
(240) 402-6032
Stacie.Gutowski@fda.hhs.gov

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Hi Kim,

(b)(4)

Stacie Gutowski, Ph.D.

Biomedical Engineer

ODE/DNPMD/NSDB

WO 66, Rm 2656

10903 New Hampshire Avenue

Silver Spring, MD 20993

(240) 402-6032

Stacie.Gutowski@fda.hhs.gov<mailto:Stacie.Gutowski@fda.hhs.gov>

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From: Kim Schmelzer [mailto:(b)(6)

Sent: Thursday, July 07, 2016 9:54 AM

To: Gutowski, Stacie

Subject: RE: (b)(4) needed for K151790

Stacie,

(b)(4)

Thank you,

Kim Schmelzer | Quality Manager

PMT Corporation | Permark

1500 Park Road Chanhassen MN 55317 USA

D: +952.470.0866 | F: +952.470.0865

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From: Gutowski, Stacie [mailto:Stacie.Gutowski@fda.hhs.gov]

Sent: Thursday, July 07, 2016 6:42 AM

To: Kim Schmelzer

Cc: k151790@docs.fda.gov<mailto:k151790@docs.fda.gov>

Records processed under FOIA Request 2024-2207; Released by CDRH on 11-13-2024

Subject: RE: (b)(4) needed for K151790

Hi Kim,

(b)(4)

Stacie Gutowski, Ph.D.

Biomedical Engineer

ODE/DNPMD/NSDB

WO 66, Rm 2656

10903 New Hampshire Avenue

Silver Spring, MD 20993

(240) 402-6032

Stacie.Gutowski@fda.hhs.gov<mailto:Stacie.Gutowski@fda.hhs.gov>

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From: Kim Schmelzer [mailto:(b)(6)

Sent: Wednesday, July 06, 2016 4:55 PM

To: Gutowski, Stacie

Cc: (b)(6) <mailto:(b)(6)>

Subject: RE: (b)(4) needed for K151790

Stacie,

(b)(4)

Let me know if you have any further questions on this.

Thank you,

Kim Schmelzer | Quality Manager

PMT Corporation | Permark

1500 Park Road Chanhassen MN 55317 USA

D: +952.470.0866 | F: +952.470.0865

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

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From: Gutowski, Stacie [mailto:Stacie.Gutowski@fda.hhs.gov]

Sent: Wednesday, July 06, 2016 12:20 PM

To: Kim Schmelzer

Subject: RE: (b)(4) needed for K151790

Hello Kim,

(b)(4)

Stacie Gutowski, Ph.D.

Biomedical Engineer

ODE/DNPMD/NSDB

WO 66, Rm 2656

10903 New Hampshire Avenue

Silver Spring, MD 20993

(240) 402-6032

Stacie.Gutowski@fda.hhs.gov<mailto:Stacie.Gutowski@fda.hhs.gov>

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Records processed under FOIA Request 2024-2207; Released by CDRH on 11-13-2024

From: Kim Schmelzer [mailto: (b)(6)

Sent: Wednesday, July 06, 2016 12:05 PM

To: Gutowski, Stacie

Subject: RE: (b)(4) needed for K151790

Stacie,

(b)(4)

Thank you,

Kim Schmelzer | Quality Manager

PMT Corporation | Permark

1500 Park Road Chanhassen MN 55317 USA

D: +952.470.0866 | F: +952.470.0865

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From: Gutowski, Stacie [mailto:Stacie.Gutowski@fda.hhs.gov]

Sent: Wednesday, July 06, 2016 10:12 AM

To: Kim Schmelzer

Cc: k151790@docs.fda.gov<mailto:k151790@docs.fda.gov>

Subject: (b)(4) needed for K151790

Hello Kim,

(b)(4)

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(b)(4)

Stacie Gutowski, Ph.D.

Biomedical Engineer

ODE/DNPMD/NSDB

WO 66, Rm 2656

10903 New Hampshire Avenue

Silver Spring, MD 20993

(240) 402-6032

Stacie.Gutowski@fda.hhs.gov<mailto:Stacie.Gutowski@fda.hhs.gov>

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(b)(4)

(b)(4)

Material Safety Data Sheet

(b)(4)

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(b)(4)

(b)(4)	MSDS

(b)(4)

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Records processed under FOIA Request 2024-2207; Released by CDRH on 11-13-2024

From: Gutowski, Stacie

Sent: Monday, March 07, 2016 2:17 PM

To: 'Kim Schmelzer'

Cc: k151790@docs.fda.gov

Subject: RE: K151790/S001 Question

Dear Ms. Schmelzer,

Thank you for your email. (b)(4)

(b)(4)

(b)(4) Please let me know if you have any further questions regarding this information.

Sincerely,

Stacie Gutowski, Ph.D.

Biomedical Engineer

ODE/DNPMD/NSDB

WO 66, Rm 2656

10903 New Hampshire Avenue

Silver Spring, MD 20993

(240) 402-6032

Stacie.Gutowski@fda.hhs.gov<mailto:Stacie.Gutowski@fda.hhs.gov>

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From: Kim Schmelzer [mailto: (b)(6)

Sent: Wednesday, March 02, 2016 2:51 PM

To: Gutowski, Stacie

Subject: RE: K151790/S001 Question

Stacie,

I hope this email finds you well.

(b)(4)

Thank you,

Kim Schmelzer | Quality Manager

PMT Corporation | Permark

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

Records processed under FOIA Request 2024-2207; Released by CDRH on 11-13-2024
1500 Park Road Chanhassen MN 55317 USA

D: +952.470.0866 | F: +952.470.0865

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

Hi Stacie – We can do a conference call tomorrow. Is there a dial in # for the call?

(b)(4)

Thanks for your help on this submittal.

- Ben

Benjamin Osa
Neurosurgery Engineering Manager
PMT Corporation
1500 Park Road
Chanhassen, MN 55317
Email: (b)(6)
(P) 952-470-0866
(F) 952-470-0865

From: Gutowski, Stacie [mailto:Stacie.Gutowski@fda.hhs.gov]
Sent: Wednesday, June 15, 2016 3:58 PM
To: Ben Osa
Cc: k151790@docs.fda.gov; (b)(6)
Subject: RE: FDA requesting teleconference with your team

Hello Ben,

(b)(4)

Stacie Gutowski, Ph.D.
Biomedical Engineer
ODE/DNPMD/NSDB
WO 66, Rm 2656
10903 New Hampshire Avenue
Silver Spring, MD 20993
(240) 402-6032
Stacie.Gutowski@fda.hhs.gov

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From: Ben Osa [mailto: (b)(6)
Sent: Wednesday, June 15, 2016 4:52 PM
To: Gutowski, Stacie
Cc: k151790@docs.fda.gov; (b)(6)
Subject: FDA requesting teleconference with your team

Hi Stacie – (b)(6)

Is there a way we can do a teleconference on that date or a day soon afterwards?

Please let me know.

Thanks,

- Ben

Benjamin Osa
Neurosurgery Engineering Manager
PMT Corporation
1500 Park Road
Chanhassen, MN 55317
Email: (b)(6)
(P) 952-470-0866
(F) 952-470-0865

From: Gutowski, Stacie [mailto:Stacie.Gutowski@fda.hhs.gov]
Sent: Wednesday, June 15, 2016 1:47 PM
To: Kim Schmelzer
Cc: k151790@docs.fda.gov
Subject: FDA requesting teleconference with your team

Hello Kim,

(b)(4) Can we setup a teleconference meeting with you and your team tomorrow afternoon at 2pm (eastern time)? Please let me know if you are available.

Sincerely,
Stacie Gutowski, Ph.D.
Biomedical Engineer
ODE/DNPMD/NSDB
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10903 New Hampshire Avenue
Silver Spring, MD 20993
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Hello Ms. Schmelzer,

We are in the process of reviewing the response for K151790 (b)(4)

(b)(4)

(b)(4)

(b)(4) Please be sure to cc the document email box above (k151790@docs.fda.gov<mailto:k151790@docs.fda.gov>). This will help us move forward with the review.

Sincerely,

Stacie Gutowski, Ph.D.

Biomedical Engineer

ODE/DNPMD/NSDB

WO 66, Rm 2656

10903 New Hampshire Avenue

Silver Spring, MD 20993

(240) 402-6032

Stacie.Gutowski@fda.hhs.gov<mailto:Stacie.Gutowski@fda.hhs.gov>

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(b)(4)

SUBJECT: (b)(4)

(b)(4)

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

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Public Health Service

Food and Drug Administration
Office Location
Business Address
Phone Number

Premarket Notification [510(k)] Review

Post-Review Reminders

- ☐ Final Check: Ensure your documentation accurately reflects the final recommendation prior to signature (e.g., Review Summary, data in the Device Description section, the Labeling section, etc)
- ☐ Complete CTS: Procode, Clinical Trials, Combo Product, MR compatibility
- ☐ Ensure the content of the 510(k) Summary is accurate (N/A if a 510(k) Statement was provided instead).
- ☐ For SE Decisions: Upload SE Letter, and PDFs of IFU form and 510(k) Summary (if included) in DocMan.

To add reminders, type the reminder in the text field to the left then press the Tab key.

Date: December 4, 2015

Reviewer: Stacie Gutowski, Ph.D.

Subject: Traditional 510(k)# K157190

Applicant: PMT Corporation

Device Trade Name: Depthalon Depth Electrode

Contact Name: Kim Schmelzer

Contact Title: Quality Manager

Correspondent Firm:

Phone: 952-470-0866 **Email:** (b)(6)

Received Date: October 9, 2015

Due Date: December 8, 2015

Reg #: 882.1330 **Reg Name:** Depth Electrode

Class: II **Product Code(s):** GZL

Predicate Devices:

Submission #	Pro Code	Device Trade Name	Owner
K802152	GZL	PMT Depthalon Depth #2102	Progress Mankind Technology
K041604	GZL	Macro-micro Depth Electrode	Ad-tech Medical Instrument Corp.

(b)(5)

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

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Digital Signature Concurrence Table	
Reviewer Sign-Off	Stacie M. Gutowski -S 2015.12.04 10:06:36 -05'00'

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(b)(4)

REPORT TO: Ms. Kim Schmelzer
PMT Corporation
1500 Park Road
Chanhassen, MN 55317

TEST ARTICLE: Depthalon Depth Electrodes (b)(4)

(b)(4)

(b)(4)

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(b)(4)

(b)(4) TEST PROTOCOL

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(b)(4)

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(b)(4)

FINAL GLP REPORT: (b)(4)

(b)(4)

*Test Performed for: PMT Corporation
1500 Park Road
Chanhassen, MN 55317

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(b)(4)

SUBJECT: (b)(4)

(b)(4)

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Contains Nonbinding Recommendations

Print Form

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) #: K151790 Date Received by DCC: Jul 24, 2015

Lead Reviewer: Stacie Gutowski

Branch: NSDB Division: DNPMD Center/Office: CDRH/ODE

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 the element will be assessed during the substantive review.

Preliminary Questions Answers in the shaded blocks indicate consultations 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."		
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."		
Comments?		
3) If a Request for Designation 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: 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 is no, mark "No." If there was no RFD, skip this question.		(b)(4)
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."		
Comments?		

Records processed under FOIA Request 2024-2207; Released by CDRH on 11-13-2024

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.	(b)(4)
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	
Comments?	

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.
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.

Records processed under FOIA Request 2024-2267, Released by CDRH on 11-13-2024

Organizational Elements

Failure to include these items alone generally should not result in an RTA designation.

	Yes	No
1) Submission contains a Table of Contents	(b)(4)	
2) Each section is labeled (e.g., headings or tabs designating Device Description section, Labeling section, etc.)		
3) All pages of the submission are numbered.		
4) Type of 510(k) is identified (i.e., traditional, abbreviated, or special)		
Comments?		

Received per FOIA Request 2022-2597, Released by CDRH on 11-13-2024

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. An applicant may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criteria is considered Present (Yes). An assessment of the rationale will be considered during the review of the submission.	Yes	No	N/A	Comment
A. Administrative				
1) All content used to support the submission is written in English (including translations of test reports, literature articles, etc.)				
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				
b) Device common name				
c) Device class and panel or Classification regulation or Statement that device has not been classified with rationale for that conclusion				
3) Submission contains Indications for Use Statement with Rx and/or OTC designation (see also 21 CFR 801.109).				
4) Submission contains 510(k) Summary or 510(k) Statement				
a) Summary contains all elements per 21 CFR 807.92 *(See also* 510(k) Summary Checklist*)*				
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.				
Comments?				
6) Submission contains Class III Summary and Certification. *See recommended* content.				
7) Submission contains clinical data				
8) If submission references use of a national or international standard as part of demonstration of substantial equivalence, submission contains Standards Data Report for 510(k)s (Form 3654) or includes detailed information about how and the extent to which the standard has been followed.				

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

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

Received per eSTAR Portal on 2024-07-19 13:24

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. An applicant may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criteria is considered Present (Yes). An assessment of the rationale will be considered during the review of the submission.	Yes	No	N/A	Comment
Comments?	(b)(4)			
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.	(b)(4)			
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. 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." Once finalized, this guidance will represent the Agency's current thinking on this topic.				
Comments?	(b)(4)			

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.	(b)(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.				
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.				
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.				
c) A list and description of each device for which clearance is requested.				
Comments?	(b)(4)			

Received per eSTAR Portal on 05-29-2024, Reviewed by CDRH on 07-19-2024

Elements of a Complete Submission (RTA Items)
(21 CFR 807.87 unless otherwise indicated)

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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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models were not tested, please provide justification for why testing is not necessary on all models.				
12) Submission contains representative engineering drawing(s), schematics, illustrations and/or figures of the device that are clear, legible, labeled, and include dimensions.				
13) If device is 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.				
b) Submission includes a description (as detailed in item 11(a) and (b) and 12 above) of each component or accessory.				
c) A 510(k) number is provided for each component or accessory that received a prior 510(k) clearance.				

(b)(4)

Comments? (b)(4)

C. Substantial Equivalence Discussion

14) Submitter has identified a predicate device.				
a) Predicate's 510(k) number, trade name, and model number (if applicable) provided. For predicates that are preamendments devices, information is provided to document preamendments status. *Information regarding* documenting preamendment status *is available online.*				
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.				
15) Submission includes a comparison of the following for the predicate(s) and subject device				
a) Indications for Use				
b) Technology, including features, materials, and principles of operation				
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))				

(b)(4)

Comments? (b)(4)

Received per eSubmitter on: Aug 21, 2024, Reviewed by CDRH on: 10-15-2024

Elements of a Complete Submission (RTA Items)
(21 CFR 807.87 unless otherwise indicated)

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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. An applicant may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criteria is considered Present (Yes). An assessment of the rationale will be considered during the review of the submission.	Yes	No	N/A	Comment
(b)(4)				

D. Proposed Labeling (see also 21 CFR part 801)

If *in vitro* diagnostic (IVD) device, criteria 17 & 19 may be omitted.

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.	(b)(4)
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).	
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) AND - includes directions for layperson (see 21 CFR 801.5) OR submission states that device qualifies for exemption per 21 CFR 801 Subpart D	
Comments? (b)(4)	
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]	(b)(4)
19) General labeling provisions	
a) Labeling includes name and place of business of the manufacturer, packer, or distributor (21 CFR 801.1).	
b) Labeling includes device common or usual name. (21 CFR 801.61)	
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.	
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.	
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.	
21) If the device is an in vitro diagnostic device, provided labeling includes all applicable information required per 21 CFR 809.10.	

Received per eSubmitter from FDA Right Size Pilot Program by CDRH on 11-13-2024

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. An applicant may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criteria is considered Present (Yes). An assessment of the rationale will be considered during the review of the submission.	Yes	No	N/A	Comment
E. Sterilization				
If IVD device and sterilization is not applicable, select "N/A" and criteria below will be omitted from checklist.				
Submission states that the device and/or accessories are: (one of the below must be checked)				
X provided sterile				
X provided non-sterile but sterilized by the end user				
non-sterile when used				
Information regarding the sterility status of the device is not provided.				
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.				
22) Assessment of the need for sterilization information				
a) Identification of device, and/or accessories, and/or components that are provided sterile.				
b) Identification of device, and/or accessories, and/or components that are end user sterilized.				
c) Identification of device, and/or accessories, and/or components that are reusable and cleaning /disinfection instructions are provided.				
Comments? (b)(4)				
23) If the device, and/or accessory, and/or a component is provided sterile:				
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 levels of sterilant residuals remaining on the device and sterilant residual limits.				
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) is stated.				
24) If the device, and/or accessory, and/or a component is end user sterilized:				
a) Sterilization method is stated for each component (including parameters such as dry time for steam sterilization, radiation dose, etc.).				

(b)(4)

(b)(4)

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(21 CFR 807.87 unless otherwise indicated)

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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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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) Submission includes description of packaging and packaging contents (e.g., if multiple devices are included within the same package, Tyvek packaging, etc.).				
d) Submission includes sterilization instructions for end user.				
Comments? (b)(4)				
25)				
a) If there are requirements regarding sterility, such as special 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.				
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.				
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.				
F. Shelf Life				
26) Proposed shelf life/expiration date stated				
27) For sterile device, submission includes summary of methods used to establish that device will remain sterile through the proposed shelf life or a rationale for why testing to establish shelf life is not applicable.				
Comments? (b)(4)				
28) Submission includes summary of methods used to establish that device performance is not adversely affected by aging or includes a rationale for why the storage conditions are not expected to affect device safety or effectiveness.				
G. Biocompatibility				
If IVD device, select "N/A" and the below criteria will be omitted from checklist.				
Submission states that there: (one of the below must be checked)				
X are direct or indirect (e.g., through fluid infusion) patient contacting components.				

(b)(4)

(b)(4)

(b)(4)

Received per eSTAR Pilot Program by CDRH on 12-19-24

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. An applicant may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criteria is considered Present (Yes). An assessment of the rationale will be considered during the review of the submission.	Yes	No	N/A	Comment
are no direct or indirect (e.g., through fluid infusion) patient-contacting components.				
Information regarding the patient contact status of the device is not provided.				
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.				
29) Submission includes list of patient-contacting device components and associated materials of construction, including identification of color additives, if present	(b)(4)			
Comments?	(b)(4)			
30) Submission identifies contact classification (e.g., surface-contacting, less then 24 hour duration, etc.)	(b)(4)			
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).				
Comments?	(b)(4)			
H. Software				
Submission states that the device: (one of the below must be checked)				
does contain software/firmware.				
× does not contain software/firmware.				
Information regarding whether the device contains software is not provided.				
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.				
I. EMC and Electrical Safety				
Submission states that the device: (one of the below must be checked)				
does require EMC and Electrical Safety evaluation.				
× does not require EMC and Electrical Safety evaluation.				
Information regarding whether the device requires EMC and Electrical Safety evaluation is not provided.				

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

Received per Section 520(g)(1)(B) of the FD&C Act by CDRH on 11-13-2024

Elements of a Complete Submission (RTA Items)
(21 CFR 807.87 unless otherwise indicated)

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This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.				
J. Performance Data - General If IVD device, select "N/A" and the below criteria will be omitted from checklist. Performance data criteria relating to IVD devices will be addressed in Section K.				
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.				
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.				
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 approach.				
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.				
38) If literature is referenced in the submission, submission includes:				
39) For each completed nonclinical (i.e., animal) study conducted				
K. Performance Characteristics - In Vitro Diagnostic Devices Only **(Also see 21 CFR 809.10(b)(12))**				
Submission states that the device: (one of the below must be checked)				
is an in vitro diagnostic device.				
× is not an in vitro diagnostic device.				

(b)(4)

Records processed under FOIA Request 2024-2207; Released by CDRH on 11-13-2024

Decision: (b)(4)

If Accept, notify applicant.

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

Digital Signature Concurrence Table	
Reviewer Sign-Off	Stacie M. Gutowski -S 2015.07.30 09:18:20 -04'00'
Branch Chief Sign-Off (digital signature optional)*	
Division Sign-Off (digital signature optional)*	

* Branch and Division review of checklist and concurrence with decision required. Branch and Division digital signature optional.

Records processed under FOIA Request 2024-2207; Released by CDRH on 11-13-2024

(b)(4)

SUBJECT: (b)(4)

(b)(4)

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

Records processed under FOIA Request 2024-2207; Released by CDRH on 11-13-2024

(b)(4)

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(b)(4)

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(b)(4)

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(b)(4)

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(b)(4)

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Records processed under FOIA Request 2024-2207; Released by CDRH on 11-13-2024

From: Kim Schmelzer [mailto:(b)(6)]
Sent: Thursday, June 23, 2016 2:31 PM
To: Gutowski, Stacie
Cc: (b)(6)
Subject: Follow-up deficiency information for K151790

June 23, 2016

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

RE: K157190/S002
Device Name: PMT Platinum Depthalon® Depth Electrodes

Stacie Gutowski, Ph.D.,

The attached information located in this email is in response to your email received at PMT Corporation on Monday June 20, 2016 regarding the premarket 510(k) notification for PMT® Platinum Depthalon® Depth Electrodes. (b)(4) Should you have any questions please contact me.

Thank you,
Kim Schmelzer | Quality Manager
PMT Corporation | Permark
1500 Park Road Chanhassen MN 55317 USA
D: +952.470.0866 | F: +952.470.0865
www.pmtcorp.com | www.permark.com

Description: pmt_logo

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

Records processed under FOIA Request 2024-2207; Released by CDRH on 11-13-2024

(b)(4)

PMT CORPORATION

Platinum Depthalon Depth Electrode

(b)(4)

(b)(4) Test

(b)(4)

April 22, 2014

(b)(4)

(b)(4)

Questions? Contact FDA/CDRH/OSEL/DD at CDRH-EOISTAFF@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2024-2207; Released by CDRH on 11-13-2024

(b)(4)

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(b)(4)

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Records processed under FOIA Request 2024-2207; Released by CDRH on 11-13-2024

PMT® Corporation
1500 PARK ROAD · CHANHASSEN, MN 55317 USA · PHONE (952) 470-0866 · 1-800-MANKIND · FAX (952) 470-0865

(b)(4)

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

Records processed under FOIA Request 2024-2207; Released by CDRH on 11-13-2024

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Document type: TECHNICAL REPORT	Document No. (b)(4)	Page 1 of 13
Document title: (b)(4)	Effective Date 7/18/07	Current Rev. (b)(4)

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Document type: TECHNICAL REPORT	Document No. (b)(4)	Page 1 of 15
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PMT®

1500 Park Road • Chanhassen, MN 55317 USA • Phone (952) 470-0866 • Fax (952) 470-0865 • www.pmtcorp.com

Indications for Use Statement

510(k) Number (if known): K151790

Device Name

PMT® Platinum Depthalon® Depth Electrodes

Indications for Use

The Platinum Depthalon® Depth Electrodes are intended for temporary (<30 day) use with recording, monitoring, and stimulation equipment for the recording, monitoring and stimulation of electrical signals in the subsurface of the brain.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use __X___ OR Over the Counter Use_____
(Per 21 CFR 801.109

(Optimal Format 1-2-96)

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

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

PMT Corporation
Kim Schmelzer
Quality Manager
1500 Park Road
Chanhassen, MN 55317

Re: K157190
Trade/Device Name: PMT Platinum Depthalon Depth Electrodes
Regulation Number: 21 CFR 882.1330
Regulation Name: Depth Electrode
Regulatory Class: Class II
Product Code: GZL
Dated: June 9, 2016
Received: October 9, 2015

Dear Kim Schmelzer:

This letter corrects our substantially equivalent letter of July 14, 2016.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

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comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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

Sincerely,

LETTER SHOULD BE DATED BEFORE SIGNING

Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

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

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(b)(4)

From: Kim Schmelzer [mailto:(b)(6)
Sent: Monday, July 11, 2016 8:56 AM
To: Gutowski, Stacie
Subject: RE: (b)(4) needed for K151790

Stacie,

(b)(4)

Thank you,
Kim Schmelzer | Quality Manager
PMT Corporation | Permark
1500 Park Road Chanhassen MN 55317 USA
D: +952.470.0866 | F: +952.470.0865
www.pmtcorp.com | www.permark.com

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From: Gutowski, Stacie [mailto:Stacie.Gutowski@fda.hhs.gov]
Sent: Monday, July 11, 2016 6:52 AM
To: Kim Schmelzer
Subject: RE: (b)(4) needed for K151790

Hello Kim,

(b)(4)

Sincerely,
Stacie Gutowski, Ph.D.
Biomedical Engineer
ODE/DNPMD/NSDB
WO 66, Rm 2656
10903 New Hampshire Avenue
Silver Spring, MD 20993
(240) 402-6032
Stacie.Gutowski@fda.hhs.gov

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From: Kim Schmelzer [mailto:(b)(6)
Sent: Friday, July 08, 2016 4:58 PM
To: Gutowski, Stacie
Cc: (b)(6)
Subject: RE: (b)(4) needed for K151790

Stacie,

(b)(4) Have a wonderful weekend.

Thank you,
Kim Schmelzer | Quality Manager
PMT Corporation | Permark
1500 Park Road Chanhassen MN 55317 USA
D: +952.470.0866 | F: +952.470.0865
www.pmtcorp.com | www.permark.com

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From: Gutowski, Stacie [mailto:Stacie.Gutowski@fda.hhs.gov]
Sent: Friday, July 08, 2016 2:15 PM
To: Kim Schmelzer

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Cc: k151790@docs.fda.gov
Subject: RE: (b)(4) needed for K151790

Hi Kim,

(b)(4)

Stacie Gutowski, Ph.D.
Biomedical Engineer
ODE/DNPMD/NSDB
WO 66, Rm 2656
10903 New Hampshire Avenue
Silver Spring, MD 20993
(240) 402-6032
Stacie.Gutowski@fda.hhs.gov

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From: Kim Schmelzer [mailto (b)(6)
Sent: Thursday, July 07, 2016 9:54 AM
To: Gutowski, Stacie
Subject: RE: (b)(4) needed for K151790

Stacie,

(b)(4)

Thank you,
Kim Schmelzer | Quality Manager
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From: Gutowski, Stacie [mailto:Stacie.Gutowski@fda.hhs.gov]
Sent: Thursday, July 07, 2016 6:42 AM
To: Kim Schmelzer
Cc: k151790@docs.fda.gov
Subject: RE: (b)(4) needed for K151790

Hi Kim,

(b)(4)

Stacie Gutowski, Ph.D.
Biomedical Engineer
ODE/DNPMD/NSDB
WO 66, Rm 2656
10903 New Hampshire Avenue
Silver Spring, MD 20993
(240) 402-6032
Stacie.Gutowski@fda.hhs.gov

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From: Kim Schmelzer [mailto: (b)(6)
Sent: Wednesday, July 06, 2016 4:55 PM
To: Gutowski, Stacie
Cc: (b)(6)
Subject: RE: (b)(4) needed for K151790

Stacie,

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(b)(4)

Let me know if you have any further questions on this.

Thank you,
Kim Schmelzer | Quality Manager
PMT Corporation | Permark
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Sent: Wednesday, July 06, 2016 12:20 PM
To: Kim Schmelzer
Subject: RE: (b)(4) needed for K151790

Hello Kim,

(b)(4)

Stacie Gutowski, Ph.D.
Biomedical Engineer
ODE/DNPMD/NSDB
WO 66, Rm 2656
10903 New Hampshire Avenue
Silver Spring, MD 20993
(240) 402-6032
Stacie.Gutowski@fda.hhs.gov

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From: Kim Schmelzer [mailto: (b)(6)
Sent: Wednesday, July 06, 2016 12:05 PM
To: Gutowski, Stacie
Subject: RE: (b)(4) needed for K151790

Stacie,

(b)(4)

Thank you,
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From: Gutowski, Stacie [mailto:Stacie.Gutowski@fda.hhs.gov]
Sent: Wednesday, July 06, 2016 10:12 AM
To: Kim Schmelzer
Cc: k151790@docs.fda.gov
Subject: (b)(4) needed for K151790

Hello Kim,

(b)(4)

Stacie Gutowski, Ph.D.
Biomedical Engineer
ODE/DNPMD/NSDB
WO 66, Rm 2656
10903 New Hampshire Avenue
Silver Spring, MD 20993
(240) 402-6032
Stacie.Gutowski@fda.hhs.gov

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PMT CORPORATION

Platinum Depthalon Depth Electrode

(b)(4)

(b)(4) Evaluation

(b)(4)

April 2, 2014

(b)(4)

(b)(4)

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SECTION I (continued) UTILIZATION OF STANDARDS

Additional Standards cited in this application:

ANSI/AAMI/ISO 10993-1:2003	Biological Evaluation of Medical Devices Part 1
ANSI/AAMI/ISO 10993-12:2012	Biological Evaluation of Medical Devices Part 12 – Sample preparation and reference materials.
ANSI/AAMI/ISO 10993-5:2009	Biological Evaluation of Medical Devices Part 5 – Tests for in vitro cytotoxicity
ANSI/AAMI/ISO 10993-10:2010	Biological Evaluation of Medical Devices Part 10 – Tests for irritation and delayed-type hypersensitivity
ANSI/AAMI/ISO 10993-10:2010	Biological Evaluation of Medical Devices Part 10 – Tests for irritation and delayed-type hypersensitivity
ANSI/AAMI/ISO 10993-10:2010	Biological Evaluation of Medical Devices Part 10 – Tests for irritation and delayed-type hypersensitivity
ANSI/AAMI/ISO 10993-11:2006	Biological Evaluation of Medical Devices Part 11 – Tests for Systemic Toxicity
ISO 10993-3:2003	Biological Evaluation of Medical Devices Part 3 – Tests for Genotoxicity, Carcinogenicity and Reproductive Toxicity
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ISO 10993-3:2003	Biological Evaluation of Medical Devices Part 3 – Tests for Genotoxicity, Carcinogenicity and Reproductive Toxicity
ISO 10993-6:2007	Biological Evaluation of Medical Devices Part 6 – Tests for Local Effects After Implantation

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FDA/CDRH/DCC

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October 8, 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

Reference: K151790 – PMT® Depthalon® Depth Electrode (b)(4)

To Whom It May Concern:

Per your letter dated 10/8/2015 received via email. PMT hereby submits this replacement eCopy for the PMT Platinum Depthalon Depth Electrode 510(k) submittal K151790.

This submission contains confidential commercial and trade secret information. We respectfully request that you give this notification the maximum protection provided by law.

Thank you in advance for your consideration of this application. If there are any questions, please contact me at 952-470-0866 or (b)(6)

Sincerely,

(b)(6)

Kim Schmelzer
Quality Manager
PMT Corporation

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K151790/S001

1500 Park Road • Chanhassen, MN 55317 USA • Phone (952) 470-0866 • Fax (952) 470-0865 • www.pmtcorp.com

FDA/CDRH/DCC
OCT 08 2015
RECEIVED

September 30, 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

Reference: K151790 – PMT® Platinum Depthalon® Depth Electrode (b)(4)

To Whom It May Concern:

Per your email received 7/31/2015. PMT hereby submits this replacement paper copy and eCopy for the Platinum Depthalon Depth Electrode product family 510(k) submittal K151790.

There have been no previous submissions for the subject device.

This submission contains confidential commercial and trade secret information. We respectfully request that you give this notification the maximum protection provided by law.

Thank you in advance for your consideration of this application. If there are any questions, please contact me at 952-470-0866 or (b)(6)

Sincerely,

(b)(6)

Kim Schmelzer
Quality Manager
PMT Corporation

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

Records processed under FOIA Request 2024-2207; Released by CDRH on 11-13-2024

(b)(4)

SUBJECT: (b)(4)

(b)(4)

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Processed by CDRH on Dec 11 2021

Memorandum

Biocompatibility Review

Date:	November 30, 2015
To:	Stacie Gutowski, Ph.D., Lead Reviewer DNPMD/NSDB
From:	Dhanya Williams, M.S. Interdisciplinary Scientist, DNPMD/NNDB
Reviewer Electronic Signature:	Dhanya K. Williams -S 2015.11.30 22:46:35 -05'00'
Subject:	K151790/S001
Applicant:	PMT Corporation 1500 Park Road Chanhassen, MN 55317
Device (Trade name):	PMT Platinum Depthalon® Depth Electrodes
Device (Regulation name):	Depth Electrode
Contact:	Kim Schmelzer, Quality Manager PMT Corporation 1500 Park Road Chanhassen, MN 55317 Phone: 952-470-0866 Fax: 952-470-0865 Email: (b)(6)

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ORIGINAL

PMT CORPORATION

Document type: TECHNICAL REPORT	Document No. (b)(4)	Page 1 of 5
Document title: (b)(4)	Effective Date 4/30/12	Current Rev. (b)(4)

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Records processed under FOIA Request 2015-4007; Released by CDRH on 11-13-2024

Contains Nonbinding Recommendations

Print Form

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.
FDA recommends that the submitter include this completed checklist as part of the submission.

510(k) #: K151790 Date Received by DCC: Oct 9, 2015

Lead Reviewer: Stacie Gutowski

Branch: NSDB Division: DNPMD Center/Office: CDRH/ODE

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 the RTA review and that the element will be assessed during substantive review.

IMPORTANT - Many checklist elements include additional details regarding information to address the element that can be seen by hovering over the element (Example - Element 4 in Section A of the checklist).

Preliminary Questions

Answers in the shaded blocks indicate consultation with a Center advisor is needed. (Boxes checked in this section represent FDAs preliminary assessment of these questions at the time of administrative review.)	Yes	No	N/A
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 Product 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."			
Comments:			
2. Is the submission 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 submission is not with the appropriate Center or you are unsure, consult with the CDRH Jurisdictional Officer or CBER Product Jurisdiction Liaison to determine the appropriate action and inform your division management. *Provide a summary of the Jurisdictional Officer's/Liaison's determination.* If submission should not be reviewed by your Center mark "No."			(b)(4)
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: **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 the CBER Product 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, mark "N/A."			
Comments:			

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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."

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.

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) 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

If no clinical studies have been submitted, mark "N/A."

Comments:

(b)(4)

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

Records processed under FOIA Request 2024-2267, Released by CDRH on 11-13-2024

Organizational Elements

Failure to include these items should not result in an RTA designation.

*Submitters including the checklist with their submission should identify the page numbers where requested information located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	*Page #
1) Submission contains a Table of Contents			
2) Each section is labeled (e.g., headings or tabs designating Device Description section, Labeling section, etc.)			
3) All pages of the submission are numbered.			
4) Type of 510(k) is identified (i.e., Traditional, Abbreviated, or Special).			

(b)(4)

Comments:

Elements of a Complete Submission (RTA Items)
(21 CFR 807.87 unless otherwise indicated)

Submission should be designated RTA if not addressed.

- Any "No" answer will result in a "Refuse to Accept" decision; however, FDA staff has discretion to determine whether missing items are needed to ensure that the submission is administratively complete to allow the submission to be accepted or to request missing checklist items interactively from submitters during RTA review.
- 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.

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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. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	N/A	Comment	*Page #
A. Administrative					
1) All content used to support the submission is written in English (including translations of test reports, literature articles, etc.)					
2) Submission identifies the following (FDA recommends use of the CDRH Premarket Review Submission Cover Sheet form [Form 3514]):					
a) Device trade/proprietary name					
b) Device class and panel or Classification regulation or Statement that device has not been classified with rationale for that conclusion					
3) Submission contains an Indication for Use Statement with Rx and/or OTC designated (see also 21 CFR 801.109, and FDA's guidance "Alternative to Certain Prescription Devices Labeling Requirements.") *See recommended format. (http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM360431.pdf).*					
4) Submission contains a 510(k) Summary or 510(k) Statement.					
5) Submission contains a Truthful and Accuracy Statement per 21 CFR 807.87(k) *See recommended format.* *(http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm142707.htm).*					
6) Submission is a Class III 510(k) device.					
7) Submission contains clinical data					
8) The submission identifies prior submissions for the same device included in the current submission (e.g., submission numbers for a prior not substantially equivalent [NSE] determination, prior deleted or withdrawn 510(k), Pre-Submission, IDE, PMA, etc.). **OR** States that there were no prior submissions for the subject device.					
a) If there were prior submissions, the submitter has identified where in the current submission any issues related to a determination of substantial equivalence from prior submissions for this device are addressed.					
B. Device Description					
9) The device has a device-specific guidance document, special controls document, and/or requirements in a device-specific regulation regarding device description that is applicable to the subject device.					
10) Descriptive information is present and consistent within the submission (e.g., the device description section is consistent with the device description in the labeling).					
11) The submission includes descriptive information for the device, including the following:					
a) A description of the principle of operation or mechanism of action for achieving the intended effect.					
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.					
c) A list and description of each device for which clearance is requested					

(b)(4)

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d) Submission contains representative engineering drawing(s), schematics, illustrations, photos and/or figures of the device. **OR** Submission includes a statement that engineering drawings, schematics, etc. are not applicable to the device (e.g., device is a reagent and figures are not pertinent to describe the device).					
12) Device is 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.					
b) Submission includes a description (as detailed in item 11(a), 11(b) and 11(d) above) of each component or accessory.					
c) A 510(k) number is provided for each component or accessory that received a prior 510(k) clearance **AND** A statement is provided that identifies components or accessories that have not received prior 510(k) clearance.					

(b)(4)

Comments:

(b)(4)

C. Substantial Equivalence Discussion

13) Submitter has identified a predicate device(s), including the following information:					
a) Predicate device identifier provided (e.g., 510(k) number, de novo number, reclassified PMA number, regulation number if exempt or statement that the predicate is a preamendment device). 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/DeviceRegulationandGuidance/MedicalDeviceQualityandCompliance/ucm379552.htm).*					
b) The identified predicate(s) is consistent throughout the submission (e.g., 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).					
14) Submission includes a comparison of the following for the predicate(s) and subject device and a discussion why any differences between the subject and predicate(s) do not impact safety and effectiveness [see section 513(i)(1)(A) of the FD&C Act and 21 CFR 807.87(f)] *See "The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]" guidance document for more information on comparing intended use and technological characteristics.*					
a) Indications for Use					
b) Technology, including features, materials, and principles of operation					

(b)(4)

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D. Proposed Labeling (see also 21 CFR part 801 and 809 as applicable)

15) Submission includes proposed package labels and labeling (e.g., instructions for use, package insert, operator's manual).

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).

b) Labeling includes:
- Statements of conditions, purposes or uses for which the device is intended (e.g., hazards, warnings, precautions, contraindications) (21 CFR 801.5)

AND

- Includes adequate directions for use (see 21 CFR 801.5)

OR

- Submission states that device qualifies for exemption per 21 CFR 801 Subpart D

(b)(4)

Comments: (b)(4)

16) Labeling includes name and place of business of the manufacturer, packer, or distributor (21 CFR 801.1).

17) Labeling includes the prescription statement [see 21 CFR 801.109(b)(1)] or Rx Only symbol (see also Section 502(a) of the FD&C Act and FDA's guidance "Alternative to Certain Prescription Device Labeling Requirements").

18) The device has a device-specific guidance document, special controls document, and/or requirements in a device-specific regulation regarding labeling that is applicable to the subject device.

19) If the device is an in vitro diagnostic device, provided labeling includes all applicable information required per 21 CFR 809.10.

(b)(4)

E. Sterilization

If an *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, and/or components are: (one of the below must be checked)

(b)(4)	Provided sterile, intended to be single-use
	Requires processing during its use-life
	Non-sterile when used (and no processing required)
	Information regarding the sterility status of the device is not provided. (If this box is checked, please also check one of the two boxes below.)
	Sterility status not needed for this device (e.g., software-only device)
	Sterility status needed or need unclear

This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.
Please refer to the guidance document titled "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling" for additional information.

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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. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	N/A	Comment	*Page #
20) Assessment of the need for cleaning and subsequent disinfection or sterilization information					
a) Identification of device, and/or accessories, and/or components that are provided sterile.					
b) Identification of device, and/or accessories, and/or components that are end user sterilized or disinfected.					
c) Identification of device, and/or accessories, and/or components that are reusable.					
21) If the device, and/or accessory, and/or a component is provided sterile:					
a) Sterilization method is stated for each component (including dose for radiation sterilization).					
b) A description of method to validate the sterilization parameters is provided for each proposed sterilization method (e.g., half-cycle method and full citation of FDA-recognized standard, including date).					
c) For devices sterilized using chemical sterilants such as ethylene oxide (EO) and hydrogen peroxide, submission states maximum levels of sterilant residuals remaining on the device and sterilant residual limits.					
d) Sterility Assurance Level (SAL) is stated.					
e) Submission includes description of packaging.					
f) For products labeled "non-pyrogenic," a description of the method used to make the determination stated (e.g., limulus amebocyte lysate [LAL]).					
22) If the device, and/or accessory, and/or a component is reusable or end user sterilized or disinfected:					
a) Cleaning method is provided in labeling for each device, and/or accessory, and/or component.					
b) Disinfection method is provided in labeling for each device, and/or accessory, and/or component.					
c) Sterilization method is provided in labeling for each device and/or accessory, and/or component.					
d) Device types in this submission are listed in Appendix E of the FDA's guidance "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling."					
i) If device types in this submission are included in Appendix E of the reprocessing guidance, the submission includes protocols and test reports for validating the reprocessing instructions.					
Comments:					
23) The device has a device-specific guidance document, special controls document, and/or requirement in a device-specific regulation regarding sterility and/or reprocessing that is applicable to the subject device.					

(b)(4)

(b)(4)

(b)(4)

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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. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	N/A	Comment	*Page #
F. Shelf Life					
24) Proposed shelf life/expiration date stated **OR** Statement that shelf-life is not applicable because of low likelihood of time-dependent product degradation					
25) For a sterile device, submission includes summary of methods used to establish that device packaging will maintain a sterile barrier for the entirety of the proposed shelf life.					
26) Submission includes summary of methods used to establish that device performance is maintained for the entirety of the proposed shelf-life (e.g., mechanical properties, coating integrity, pH, osmolality, etc.). **OR** Statement why performance data is not needed to establish maintenance of device performance characteristics over the shelf-life period.					
G. Biocompatibility					
If an 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 direct or indirect patient-contacting components.					
Are no direct or indirect patient-contacting components.					
Information regarding patient contact status of the device is not provided (if this box checked, please also check one of the two boxes below).					
Patient contact information not needed for this device (e.g., software-only device)					
Patient contact information needed or need unclear					
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.					
27) Submission includes a list identifying each of patient-contacting device component (e.g., implant, delivery catheter) and associated materials of construction for each component, including identification of color additives, if present.					
28) Submission identifies contact classification (e.g., surface-contacting, less then 24 hour duration) for each patient-contacting device component (e.g., implant, delivery catheter)					
29) 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).					
H. Software					
Submission states that the device: (one of the below must be checked)					
Does contain software/firmware					

(b)(4)

(b)(4)

(b)(4)

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

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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. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	N/A	Comment	*Page #
X Does not contain software/firmware					
Information on whether device contains software/firmware is not provided. (If this box is checked, please also check one of the two boxes below.)					
Software/firmware information not needed for this device (e.g., surgical suture, condom)					
Software/firmware information is needed or need unclear					
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.					

I. Electrical Safety and EMC

Electrical Safety Submission states that the device: (one of the below must be checked)					
(b)(4) Does require electrical safety evaluation					
Does not require electrical safety evaluation					
Information on whether device requires electrical safety evaluation is not provided. (If this box is checked, please also check one of the two boxes below.)					
Electrical safety information not needed for this device (e.g., surgical suture, condom)					
Electrical safety information is needed or need unclear					
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.					
EMC Submission states that the device: (one of the below must be checked)					
(b)(4) Does require EMC evaluation					
Does not require EMC evaluation					
Information on whether device requires EMC evaluation is not provided. (If this box is checked, please also check one of the two boxes below.)					
EMC information not needed for this device (e.g., surgical suture, condom)					
EMC information is needed or need unclear					
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.					

J. Performance Data - General

If an in vitro diagnostic (IVD) device, select "N/A." The criteria in this section will be omitted from checklist if "N/A" is selected. Performance data criteria relating to IVD devices is addressed in Section K.					
34) 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.	(b)(4)				
a) Submission includes an explanation of how the data generated from each test report supports a finding of substantial equivalence (e.g., comparison to predicate device testing, dimensional analysis, etc.).					

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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. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	N/A	Comment	*Page #
35) The device has a device-specific guidance document, special controls document, and/ or requirements in a device-specific regulation regarding performance data that is applicable to the subject device.	(b)(4)				
36) If literature is referenced in the submission, submission includes:					
37) For each completed animal study, the submission provides the following:					

K. Performance Characteristics - In Vitro Diagnostic Devices Only

(Also see 21 CFR 809.10(b)(12))

Submission states that the device: (one of the below must be checked)			
(b)(4)	is an in vitro diagnostic device.		
	is not an in vitro diagnostic device.		

If "is not" is selected, the performance data-related criteria below are omitted from the checklist.

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Decision: ◌ Accept ◌ Refuse to Accept

If Accept, notify applicant.

If Refuse to Accept, notify applicant electronically and include a copy of this checklist.

Digital Signature Concurrence Table	
Reviewer Sign-Off	
Branch Chief Sign-Off (digital signature optional)*	
Division Sign-Off (digital signature optional)*	

* Branch and Division review of checklist and concurrence with decision required. Branch and Division digital signature optional.

Dear Kim,
Thank you for your email (b)(4) We are finalizing our review at this time and you should receive a more formal communication from us in the form of a letter within the next several business days.

Sincerely,
Stacie Gutowski, Ph.D.
Biomedical Engineer
ODE/DNPMD/NSDB
WO 66, Rm 2656
10903 New Hampshire Avenue
Silver Spring, MD 20993
(240) 402-6032
Stacie.Gutowski@fda.hhs.gov

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https://www.research.net/s/cdrhcustomerservice?O=400&D=460&B=462&E=&S=E

From: Kim Schmelzer [mailto:(b)(6)
Sent: Friday, December 04, 2015 1:17 PM
To: Gutowski, Stacie
Subject: RE: K151790/S001 Follow-up Information Request

Stacie,

(b)(4)

Sincerley,
Kim Schmelzer | Quality Manager
PMT Corporation | Permark
1500 Park Road Chanhassen MN 55317 USA
D: +952.470.0866 | F: +952.470.0865
Toll Free: 1.800.MANKIND (626-5463)
www.pmtcorp.com | www.permark.com

Description: pmt_logo

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From: Gutowski, Stacie [mailto:Stacie.Gutowski@fda.hhs.gov]
Sent: Monday, October 19, 2015 5:37 PM
To: Kim Schmelzer
Cc: k151790@docs.fda.gov
Subject: RE: K151790/S001 Follow-up Information Request

Dear Kim,
Thank you for the additional information. We will incorporate this into our review.

Sincerely,
Stacie Gutowski, Ph.D.
Biomedical Engineer
ODE/DNPMD/NSDB
WO 66, Rm 2656
10903 New Hampshire Avenue
Silver Spring, MD 20993
(240) 402-6032
Stacie.Gutowski@fda.hhs.gov

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From: Kim Schmelzer [mailto:(b)(6)
Sent: Monday, October 19, 2015 5:04 PM
To: Gutowski, Stacie
Subject: RE: K151790/S001 Follow-up Information Request

Staci,

I hope you had a good weekend!

Records processed under FOIA Request 2024-2207; Released by CDRH on 11-13-2024

(b)(4)

Let me know if you have any further questions or concerns.

Thank you,
Kim Schmelzer | Quality Manager
PMT Corporation | Permark
1500 Park Road Chanhassen MN 55317 USA
D: +952.470.0866 | F: +952.470.0865
Toll Free: 1.800.MANKIND (626-5463)
www.pmtcorp.com | www.permark.com

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From: Gutowski, Stacie [mailto:Stacie.Gutowski@fda.hhs.gov]
Sent: Friday, October 16, 2015 7:56 AM
To: Kim Schmelzer
Cc: k151790@docs.fda.gov
Subject: RE: K151790/S001 Follow-up Information Request

Dear Ms. Schmelzer,

(b)(4)

Please let me know if you have any questions.
Stacie Gutowski, Ph.D.
Biomedical Engineer
ODE/DNPMD/NSDB

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

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WO 66, Rm 2656
10903 New Hampshire Avenue
Silver Spring, MD 20993
(240) 402-6032
Stacie.Gutowski@fda.hhs.gov

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https://www.research.net/s/cdrhcustomerservice?O=400&D=460&B=462&E=&S=E

From: Kim Schmelzer [mailto:(b)(6)]
Sent: Wednesday, October 14, 2015 2:15 PM
To: Gutowski, Stacie
Cc: k151790@docs.fda.gov
Subject: RE: K151790/S001 Follow-up Information Request

Stacie,

Thank you for your prompt reviewed and response. It is greatly appreciated.

(b)(4)

Let me know if you have any questions or need clarification.

Thank you,
Kim Schmelzer | Quality Manager
PMT Corporation | Permark
1500 Park Road Chanhassen MN 55317 USA
D: +952.470.0866 | F: +952.470.0865
Toll Free: 1.800.MANKIND (626-5463)
www.pmtcorp.com | www.permark.com

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From: Gutowski, Stacie [mailto:Stacie.Gutowski@fda.hhs.gov]
Sent: Wednesday, October 14, 2015 11:38 AM
To: (b)(6)
Cc: k151790@docs.fda.gov
Subject: K151790/S001 Follow-up Information Request

Ms. Schmelzer,
We have completed administrative review of your submission (K151790) and have accepted the file for substantive review. (b)(4) (b)(4) Please email me with the updated documents, and be sure to cc the docs.fda.gov email address above on all future communications for this file. You only need to send the documentation for the items requested, no need to send the whole submission again.
Please let me know if you have any questions.

Stacie Gutowski, Ph.D.
Biomedical Engineer
ODE/DNPMD/NSDB
WO 66, Rm 2656
10903 New Hampshire Avenue
Silver Spring, MD 20993
(240) 402-6032
Stacie.Gutowski@fda.hhs.gov

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received:
https://www.research.net/s/cdrhcustomerservice?O=400&D=460&B=462&E=&S=E

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

Records processed under FOIA Request 2024-2207; Released by CDRH on 11-13-2024

From: Stacie Gutowski [mailto:stacie.gutowski@fda.hhs.gov]
Sent: Wednesday, October 14, 2015 11:50 AM
To: (b)(6)
Cc: Gutowski, Stacie
Subject: K151790/S001 was Accepted

October 14, 2015

Acceptance Review Notification - Accepted

An administrative acceptance review was conducted on your premarket notification (510(k)) K151790/S001, and it was found to contain all of the necessary elements and information needed to proceed with the substantive review. We will contact you should we require any additional information during the course of the substantive review. The lead reviewer assigned to your submission is Stacie Gutowski.

*** This is a system-generated email notification ***

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

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Contains Nonbinding Recommendations

Print Form

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.
FDA recommends that the submitter include this completed checklist as part of the submission.

510(k) #: K151790 Date Received by DCC: Oct 9, 2015

Lead Reviewer: Stacie Gutowski

Branch: NSDB Division: DNPMD Center/Office: CDRH/ODE

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 the RTA review and that the element will be assessed during substantive review.

IMPORTANT - Many checklist elements include additional details regarding information to address the element that can be seen by hovering over the element (Example - Element 4 in Section A of the checklist).

Preliminary Questions

Answers in the shaded blocks indicate consultation with a Center advisor is needed. (Boxes checked in this section represent FDAs preliminary assessment of these questions at the time of administrative review.)	Yes	No	N/A
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 Product 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."			
Comments:			
2. Is the submission 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 submission is not with the appropriate Center or you are unsure, consult with the CDRH Jurisdictional Officer or CBER Product Jurisdiction Liaison to determine the appropriate action and inform your division management. *Provide a summary of the Jurisdictional Officer's/Liaison's determination.* If submission should not be reviewed by your Center mark "No."			(b)(4)
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: **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 the CBER Product 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, mark "N/A."			
Comments:			

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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."

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.

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) 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

If no clinical studies have been submitted, mark "N/A."

Comments:

(b)(4)

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

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Organizational Elements

Failure to include these items should not result in an RTA designation.

*Submitters including the checklist with their submission should identify the page numbers where requested information located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	*Page #
1) Submission contains a Table of Contents	(b)(4)		
2) Each section is labeled (e.g., headings or tabs designating Device Description section, Labeling section, etc.)			
3) All pages of the submission are numbered.			
4) Type of 510(k) is identified (i.e., Traditional, Abbreviated, or Special).			
Comments:			

Elements of a Complete Submission (RTA Items)
(21 CFR 807.87 unless otherwise indicated)

Submission should be designated RTA if not addressed.

- Any "No" answer will result in a "Refuse to Accept" decision; however, FDA staff has discretion to determine whether missing items are needed to ensure that the submission is administratively complete to allow the submission to be accepted or to request missing checklist items interactively from submitters during RTA review.
- 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.

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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. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	N/A	Comment	*Page #
A. Administrative					
1) All content used to support the submission is written in English (including translations of test reports, literature articles, etc.)					
2) Submission identifies the following (FDA recommends use of the CDRH Premarket Review Submission Cover Sheet form [Form 3514]):					
a) Device trade/proprietary name					
b) Device class and panel or Classification regulation or Statement that device has not been classified with rationale for that conclusion					
3) Submission contains an Indication for Use Statement with Rx and/or OTC designated (see also 21 CFR 801.109, and FDA's guidance "Alternative to Certain Prescription Devices Labeling Requirements.") *See recommended format. (http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM360431.pdf).*					
4) Submission contains a 510(k) Summary or 510(k) Statement.					
5) Submission contains a Truthful and Accuracy Statement per 21 CFR 807.87(k) *See recommended format.* *(http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm142707.htm).*					
6) Submission is a Class III 510(k) device.					
7) Submission contains clinical data					
8) The submission identifies prior submissions for the same device included in the current submission (e.g., submission numbers for a prior not substantially equivalent [NSE] determination, prior deleted or withdrawn 510(k), Pre-Submission, IDE, PMA, etc.). **OR** States that there were no prior submissions for the subject device.					
a) If there were prior submissions, the submitter has identified where in the current submission any issues related to a determination of substantial equivalence from prior submissions for this device are addressed.					
B. Device Description					
9) The device has a device-specific guidance document, special controls document, and/or requirements in a device-specific regulation regarding device description that is applicable to the subject device.					
10) Descriptive information is present and consistent within the submission (e.g., the device description section is consistent with the device description in the labeling).					
11) The submission includes descriptive information for the device, including the following:					
a) A description of the principle of operation or mechanism of action for achieving the intended effect.					
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.					
c) A list and description of each device for which clearance is requested					

(b)(4)

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

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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. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	N/A	Comment	*Page #
d) Submission contains representative engineering drawing(s), schematics, illustrations, photos and/or figures of the device. **OR** Submission includes a statement that engineering drawings, schematics, etc. are not applicable to the device (e.g., device is a reagent and figures are not pertinent to describe the device).					
12) Device is 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.					
b) Submission includes a description (as detailed in item 11(a), 11(b) and 11(d) above) of each component or accessory.					
c) A 510(k) number is provided for each component or accessory that received a prior 510(k) clearance **AND** A statement is provided that identifies components or accessories that have not received prior 510(k) clearance.					

(b)(4)

Comments:

(b)(4)

C. Substantial Equivalence Discussion

13) Submitter has identified a predicate device(s), including the following information:					
a) Predicate device identifier provided (e.g., 510(k) number, de novo number, reclassified PMA number, regulation number if exempt or statement that the predicate is a preamendment device). 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/DeviceRegulationandGuidance/MedicalDeviceQualityandCompliance/ucm379552.htm).*					
b) The identified predicate(s) is consistent throughout the submission (e.g., 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).					
14) Submission includes a comparison of the following for the predicate(s) and subject device and a discussion why any differences between the subject and predicate(s) do not impact safety and effectiveness [see section 513(i)(1)(A) of the FD&C Act and 21 CFR 807.87(f)] *See "The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]" guidance document for more information on comparing intended use and technological characteristics.*					
a) Indications for Use					
b) Technology, including features, materials, and principles of operation					

(b)(4)

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

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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. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	N/A	Comment	*Page #

D. Proposed Labeling (see also 21 CFR part 801 and 809 as applicable)

15) Submission includes proposed package labels and labeling (e.g., instructions for use, package insert, operator's manual).

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).

b) Labeling includes:
- Statements of conditions, purposes or uses for which the device is intended (e.g., hazards, warnings, precautions, contraindications) (21 CFR 801.5)

AND

- Includes adequate directions for use (see 21 CFR 801.5)

OR

- Submission states that device qualifies for exemption per 21 CFR 801 Subpart D

(b)(4)

Comments: (b)(4)

16) Labeling includes name and place of business of the manufacturer, packer, or distributor (21 CFR 801.1).

17) Labeling includes the prescription statement [see 21 CFR 801.109(b)(1)] or Rx Only symbol (see also Section 502(a) of the FD&C Act and FDA's guidance "Alternative to Certain Prescription Device Labeling Requirements").

18) The device has a device-specific guidance document, special controls document, and/or requirements in a device-specific regulation regarding labeling that is applicable to the subject device.

19) If the device is an in vitro diagnostic device, provided labeling includes all applicable information required per 21 CFR 809.10.

(b)(4)

E. Sterilization

If an *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, and/or components are: (one of the below must be checked)

(b)(4)

- Provided sterile, intended to be single-use
- Requires processing during its use-life
- Non-sterile when used (and no processing required)
- Information regarding the sterility status of the device is not provided. (If this box is checked, please also check one of the two boxes below.)

- Sterility status not needed for this device (e.g., software-only device)
- Sterility status needed or need unclear

This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.
Please refer to the guidance document titled "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling" for additional information.

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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. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	N/A	Comment	*Page #
20) Assessment of the need for cleaning and subsequent disinfection or sterilization information					
a) Identification of device, and/or accessories, and/or components that are provided sterile.					
b) Identification of device, and/or accessories, and/or components that are end user sterilized or disinfected.					
c) Identification of device, and/or accessories, and/or components that are reusable.					
21) If the device, and/or accessory, and/or a component is provided sterile:					
a) Sterilization method is stated for each component (including dose for radiation sterilization).					
b) A description of method to validate the sterilization parameters is provided for each proposed sterilization method (e.g., half-cycle method and full citation of FDA-recognized standard, including date).					
c) For devices sterilized using chemical sterilants such as ethylene oxide (EO) and hydrogen peroxide, submission states maximum levels of sterilant residuals remaining on the device and sterilant residual limits.					
d) Sterility Assurance Level (SAL) is stated.					
e) Submission includes description of packaging.					
f) For products labeled "non-pyrogenic," a description of the method used to make the determination stated (e.g., limulus amebocyte lysate [LAL]).					
22) If the device, and/or accessory, and/or a component is reusable or end user sterilized or disinfected:					
a) Cleaning method is provided in labeling for each device, and/or accessory, and/or component.					
b) Disinfection method is provided in labeling for each device, and/or accessory, and/or component.					
c) Sterilization method is provided in labeling for each device and/or accessory, and/or component.					
d) Device types in this submission are listed in Appendix E of the FDA's guidance "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling."					
i) If device types in this submission are included in Appendix E of the reprocessing guidance, the submission includes protocols and test reports for validating the reprocessing instructions.					
Comments: (b)(4)					
23) The device has a device-specific guidance document, special controls document, and/or requirement in a device-specific regulation regarding sterility and/or reprocessing that is applicable to the subject device.					

(b)(4)

(b)(4)

(b)(4)

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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. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	N/A	Comment	*Page #
F. Shelf Life					
24) Proposed shelf life/expiration date stated **OR** Statement that shelf-life is not applicable because of low likelihood of time-dependent product degradation					
25) For a sterile device, submission includes summary of methods used to establish that device packaging will maintain a sterile barrier for the entirety of the proposed shelf life.					
26) Submission includes summary of methods used to establish that device performance is maintained for the entirety of the proposed shelf-life (e.g., mechanical properties, coating integrity, pH, osmolality, etc.). **OR** Statement why performance data is not needed to establish maintenance of device performance characteristics over the shelf-life period.					
G. Biocompatibility					
If an 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)					
(b)(4) Are direct or indirect patient-contacting components.					
(b)(4) Are no direct or indirect patient-contacting components.					
(b)(4) Information regarding patient contact status of the device is not provided (if this box checked, please also check one of the two boxes below).					
Patient contact information not needed for this device (e.g., software-only device)					
Patient contact information needed or need unclear					
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.					
27) Submission includes a list identifying each of patient-contacting device component (e.g., implant, delivery catheter) and associated materials of construction for each component, including identification of color additives, if present.					
28) Submission identifies contact classification (e.g., surface-contacting, less then 24 hour duration) for each patient-contacting device component (e.g., implant, delivery catheter)					
29) 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).					
H. Software					
Submission states that the device: (one of the below must be checked)					
Does contain software/firmware					

(b)(4)

(b)(4)

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X Does not contain software/firmware					
Information on whether device contains software/firmware is not provided. (If this box is checked, please also check one of the two boxes below.)					
Software/firmware information not needed for this device (e.g., surgical suture, condom)					
Software/firmware information is needed or need unclear					
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.					

I. Electrical Safety and EMC

Electrical Safety Submission states that the device: (one of the below must be checked)					
(b)(4) Does require electrical safety evaluation					
Does not require electrical safety evaluation					
Information on whether device requires electrical safety evaluation is not provided. (If this box is checked, please also check one of the two boxes below.)					
Electrical safety information not needed for this device (e.g., surgical suture, condom)					
Electrical safety information is needed or need unclear					
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.					
EMC Submission states that the device: (one of the below must be checked)					
(b)(4) Does require EMC evaluation					
Does not require EMC evaluation					
Information on whether device requires EMC evaluation is not provided. (If this box is checked, please also check one of the two boxes below.)					
EMC information not needed for this device (e.g., surgical suture, condom)					
EMC information is needed or need unclear					
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.					

J. Performance Data - General

If an in vitro diagnostic (IVD) device, select "N/A." The criteria in this section will be omitted from checklist if "N/A" is selected. Performance data criteria relating to IVD devices is addressed in Section K.					
34) 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.	(b)(4)				
a) Submission includes an explanation of how the data generated from each test report supports a finding of substantial equivalence (e.g., comparison to predicate device testing, dimensional analysis, etc.).					

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35) The device has a device-specific guidance document, special controls document, and/ or requirements in a device-specific regulation regarding performance data that is applicable to the subject device.	(b)(4)				
36) If literature is referenced in the submission, submission includes:					
37) For each completed animal study, the submission provides the following:					

K. Performance Characteristics - In Vitro Diagnostic Devices Only

(Also see 21 CFR 809.10(b)(12))

Submission states that the device: (one of the below must be checked)		
(b)(4)	is an in vitro diagnostic device.	
	is not an in vitro diagnostic device.	

If "is not" is selected, the performance data-related criteria below are omitted from the checklist.

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Decision: (b)(4)

If Accept, notify applicant.

If Refuse to Accept, notify applicant electronically and include a copy of this checklist.

Digital Signature Concurrence Table	
Reviewer Sign-Off	Stacie M. Gutowski -S 2015.10.14 11:43:09 -04'00'
Branch Chief Sign-Off (digital signature optional)*	
Division Sign-Off (digital signature optional)*	

* Branch and Division review of checklist and concurrence with decision required. Branch and Division digital signature optional.

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Ms. Schmelzer,

We have completed administrative review of your submission (K151790) and have accepted the file for substantive review. (b)(4) (b)(4) (b)(4) Please email me with the updated documents, and be sure to cc the docs.fda.gov email address above on all future communications for this file. You only need to send the documentation for the items requested, no need to send the whole submission again.

Please let me know if you have any questions.

Stacie Gutowski, Ph.D.

Biomedical Engineer

ODE/DNPMD/NSDB

WO 66, Rm 2656

10903 New Hampshire Avenue

Silver Spring, MD 20993

(240) 402-6032

Stacie.Gutowski@fda.hhs.gov<mailto:Stacie.Gutowski@fda.hhs.gov>

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From: Stacie Gutowski [mailto:stacie.gutowski@fda.hhs.gov]

Sent: Wednesday, October 14, 2015 11:50 AM

To: (b)(6)

Cc: Gutowski, Stacie

Subject: K151790/S001 was Accepted

October 14, 2015

Acceptance Review Notification - Accepted

An administrative acceptance review was conducted on your premarket notification (510(k)) K151790/S001, and it was found to contain all of the necessary elements and information needed to proceed with the substantive review. We will contact you should we require any additional information during the course of the substantive review. The lead reviewer assigned to your submission is Stacie Gutowski.

*** This is a system-generated email notification ***

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Hello Kim,

(b)(4)

Stacie Gutowski, Ph.D.

Biomedical Engineer

ODE/DNPMD/NSDB

WO 66, Rm 2656

10903 New Hampshire Avenue

Silver Spring, MD 20993

(240) 402-6032

Stacie.Gutowski@fda.hhs.gov<mailto:Stacie.Gutowski@fda.hhs.gov>

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From: Kim Schmelzer [mailto:(b)(6)]

Sent: Wednesday, June 29, 2016 12:15 PM

To: Gutowski, Stacie

Cc: (b)(6)

Subject: Interactive Review for K151790

Stacie,

(b)(4)

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

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(b)(4)

I hope this answers your question. Please let me know if you have any further questions.

Thank you,

Kim Schmelzer | Quality Manager

PMT Corporation | Permark

1500 Park Road Chanhassen MN 55317 USA

D: +952.470.0866 | F: +952.470.0865

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Document type: TECHNICAL PROTOCOL	Document Number: (b)(4) ORIGINAL	Page 1 of 5
Document title: (b)(4)	Effective Date 9/1/09	Current Rev. (b)(4)

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Document type: Technical Report	Document No. (b)(4)	Page 1 of 11
Document title: (b)(4)	Effective Date 12/4/00	Current Rev. (b)(4)

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Depthalon Depth Electrodes

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(b)(4) Test - (b)(4)

(b)(4)

May 9, 2016

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PMT CORPORATION

Depthalon Depth Electrodes

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PMT Corporation
510(k) Statement

510(k) Number: K151790

I certify that, in my capacity as Quality Manager of PMT Corporation, I will make available all information included in this premarket notification on safety and effectiveness within 30 days of request by any person if the device described in the premarket notification submission is determined to be substantially equivalent. The information I agree to make available will be a duplicate of the premarket notification submission, including any adverse safety and effectiveness information, but excluding all patient identifiers, and trade secret and confidential commercial information, as defined in 21 CFR 20.61.

(b)(6)

Date: 9/30/15

Kim Schmelzer
Quality Manager
PMT Corporation

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

ORIGINAL

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Document type: TECHNICAL REPORT	Document No. (b)(4)	Page 1 of 10
Document title: (b)(4)	Effective Date 7/30/2012	Current Rev. (b)(4)

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13. Proposed Labeling

(b)(4)

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

Dear applicant,

Please see corrected SE letter attached.
Please feel free to contact me if you have any questions.
Thank you,
Edwena

Edwena R. Jones
Premarket Notification (510(k)) Staff
Office of Device Evaluation
Center for Devices and Radiological Health
Food and Drug Administration
edwena.jones@fda.hhs.gov

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https://www.research.net/s/cdrhcustomerservice?O=400&D=410&B=413&E=&S=E

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(b)(4)

PMT CORPORATION

Platinum Depthalon Depth Electrode

(b)(4)

(b)(4) Test

(b)(4)

April 22, 2014

(b)(4)

(b)(4)

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

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

Dear Kim,

(b)(4)

Sincerely,
Stacie Gutowski, Ph.D.
Biomedical Engineer
ODE/DNPMD/NSDB
WO 66, Rm 2656
10903 New Hampshire Avenue
Silver Spring, MD 20993
(240) 402-6032
Stacie.Gutowski@fda.hhs.gov

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From: Kim Schmelzer [mailto:(b)(6)
Sent: Friday, December 04, 2015 2:17 PM
To: Gutowski, Stacie
Subject: RE: K151790/S001 Follow-up Information Request

Stacie,

Thank you again for your prompt response. (b)(4)

Thank you,
Kim Schmelzer | Quality Manager
PMT Corporation | Permark
1500 Park Road Chanhassen MN 55317 USA
D: +952.470.0866 | F: +952.470.0865
Toll Free: 1.800.MANKIND (626-5463)
www.pmtcorp.com | www.permark.com

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From: Gutowski, Stacie [mailto:Stacie.Gutowski@fda.hhs.gov]
Sent: Friday, December 04, 2015 12:30 PM
To: Kim Schmelzer
Cc: k151790@docs.fda.gov
Subject: RE: K151790/S001 Follow-up Information Request

Dear Kim,
Thank you for your email. (b)(4) We are finalizing our review at this time and you should receive a more formal communication from us in the form of a letter within the next several business days.

Sincerely,
Stacie Gutowski, Ph.D.
Biomedical Engineer
ODE/DNPMD/NSDB
WO 66, Rm 2656
10903 New Hampshire Avenue
Silver Spring, MD 20993
(240) 402-6032
Stacie.Gutowski@fda.hhs.gov

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From: Kim Schmelzer [mailto:(b)(6)
Sent: Friday, December 04, 2015 1:17 PM
To: Gutowski, Stacie
Subject: RE: K151790/S001 Follow-up Information Request

Stacie,

I hope this email finds you well. (b)(4)

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(b)(4)

Sincerley,
Kim Schmelzer | Quality Manager
PMT Corporation | Permark
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From: Gutowski, Stacie [mailto:Stacie.Gutowski@fda.hhs.gov]
Sent: Monday, October 19, 2015 5:37 PM
To: Kim Schmelzer
Cc: k151790@docs.fda.gov
Subject: RE: K151790/S001 Follow-up Information Request

Dear Kim,
Thank you for the additional information. We will incorporate this into our review.

Sincerely,
Stacie Gutowski, Ph.D.
Biomedical Engineer
ODE/DNPMD/NSDB
WO 66, Rm 2656
10903 New Hampshire Avenue
Silver Spring, MD 20993
(240) 402-6032
Stacie.Gutowski@fda.hhs.gov

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From: Kim Schmelzer [mailto: (b)(6)
Sent: Monday, October 19, 2015 5:04 PM
To: Gutowski, Stacie
Subject: RE: K151790/S001 Follow-up Information Request

Staci,

I hope you had a good weekend!

(b)(4)

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

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(b)(4)

Let me know if you have any further questions or concerns.

Thank you,
Kim Schmelzer | Quality Manager
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From: Gutowski, Stacie [mailto:Stacie.Gutowski@fda.hhs.gov]
Sent: Friday, October 16, 2015 7:56 AM
To: Kim Schmelzer
Cc: k151790@docs.fda.gov
Subject: RE: K151790/S001 Follow-up Information Request

Dear Ms. Schmelzer,

(b)(4)

Please let me know if you have any questions.
Stacie Gutowski, Ph.D.
Biomedical Engineer
ODE/DNPMD/NSDB
WO 66, Rm 2656
10903 New Hampshire Avenue
Silver Spring, MD 20993
(240) 402-6032
Stacie.Gutowski@fda.hhs.gov

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From: Kim Schmelzer [mailto: (b)(6)
Sent: Wednesday, October 14, 2015 2:15 PM
To: Gutowski, Stacie
Cc: k151790@docs.fda.gov
Subject: RE: K151790/S001 Follow-up Information Request

Stacie,

(b)(4)

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Let me know if you have any questions or need clarification.

Thank you,
Kim Schmelzer | Quality Manager
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Toll Free: 1.800.MANKIND (626-5463)
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From: Gutowski, Stacie [mailto:Stacie.Gutowski@fda.hhs.gov]
Sent: Wednesday, October 14, 2015 11:38 AM
To: (b)(6)
Cc: k151790@docs.fda.gov
Subject: K151790/S001 Follow-up Information Request

Ms. Schmelzer,
We have completed administrative review of your submission (K151790) and have accepted the file for substantive review. (b)(4)
(b)(4) Please email me with the updated documents, and be sure to cc the docs.fda.gov email address above on all future communications for this file. You only need to send the documentation for the items requested, no need to send the whole submission again.
Please let me know if you have any questions.

Stacie Gutowski, Ph.D.
Biomedical Engineer
ODE/DNPMD/NSDB
WO 66, Rm 2656
10903 New Hampshire Avenue
Silver Spring, MD 20993
(240) 402-6032
Stacie.Gutowski@fda.hhs.gov

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https://www.research.net/s/cdrhcustomerservice?O=400&D=460&B=462&E=&S=E

From: Stacie Gutowski [mailto:stacie.gutowski@fda.hhs.gov]
Sent: Wednesday, October 14, 2015 11:50 AM
To: (b)(6)
Cc: Gutowski, Stacie
Subject: K151790/S001 was Accepted

October 14, 2015

Acceptance Review Notification - Accepted

An administrative acceptance review was conducted on your premarket notification (510(k)) K151790/S001, and it was found to contain all of the necessary elements and information needed to proceed with the substantive review. We will contact you should we require any additional information during the course of the substantive review. The lead reviewer assigned to your submission is Stacie Gutowski.

*** This is a system-generated email notification ***

Records processed under FOIA Request 2024-2207; Released by CDRH on 11-13-2024

Ms. Schmeizer,
We have completed administrative review of your submission (K151790) and have accepted the file for substantive review. (b)(4) (b)(4) Please email me with the updated documents, and be sure to cc the docs.fda.gov email address above on all future communications for this file. You only need to send the documentation for the items requested, no need to send the whole submission again.
Please let me know if you have any questions.

Stacie Gutowski, Ph.D.
Biomedical Engineer
ODE/DNPMD/NSDB
WO 66, Rm 2656
10903 New Hampshire Avenue
Silver Spring, MD 20993
(240) 402-6032
Stacie.Gutowski@fda.hhs.gov

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https://www.research.net/s/cdrhcustomerservice?O=400&D=460&B=462&E=&S=E

From: Stacie Gutowski [mailto:stacie.gutowski@fda.hhs.gov]
Sent: Wednesday, October 14, 2015 11:50 AM
To: (b)(6)
Cc: Gutowski, Stacie
Subject: K151790/S001 was Accepted

October 14, 2015

Acceptance Review Notification - Accepted

An administrative acceptance review was conducted on your premarket notification (510(k)) K151790/S001, and it was found to contain all of the necessary elements and information needed to proceed with the substantive review. We will contact you should we require any additional information during the course of the substantive review. The lead reviewer assigned to your submission is Stacie Gutowski.

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(b)(4) TEST – (b)(4)

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FINAL GLP REPORT: (b)(4)

(b)(4) TEST – (b)(4)

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*Test Performed for: PMT Corporation
1500 Park Road
Chanhassen, MN 55317

(b)(4)

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Hello Ben,

(b)(4)

Stacie Gutowski, Ph.D.

Biomedical Engineer

ODE/DNPMD/NSDB

WO 66, Rm 2656

10903 New Hampshire Avenue

Silver Spring, MD 20993

(240) 402-6032

Stacie.Gutowski@fda.hhs.gov<mailto:Stacie.Gutowski@fda.hhs.gov>

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From: Ben Osa [mailto:(b)(6)

Sent: Wednesday, June 15, 2016 4:52 PM

To: Gutowski, Stacie

Cc: k151790@docs.fda.gov; (b)(6)

Subject: FDA requesting teleconference with your team

Hi Stacie - (b)(6)
(b)(6)

Is there a way we can do a teleconference on that date or a day soon afterwards?

Please let me know.

Thanks,

- Ben

Benjamin Osa

Neurosurgery Engineering Manager

PMT Corporation

1500 Park Road

Chanhassen, MN 55317

Email: (b)(6) <mailto:(b)(6)>

(P) 952-470-0866

(F) 952-470-0865

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

Records processed under FOIA Request 2024-2207; Released by CDRH on 11-13-2024

From: Gutowski, Stacie [mailto:Stacie.Gutowski@fda.hhs.gov]

Sent: Wednesday, June 15, 2016 1:47 PM

To: Kim Schmelzer

Cc: k151790@docs.fda.gov<mailto:k151790@docs.fda.gov>

Subject: FDA requesting teleconference with your team

Hello Kim,

(b)(4) Can we setup a teleconference meeting with you and your team tomorrow afternoon at 2pm (eastern time)? Please let me know if you are available.

Sincerely,

Stacie Gutowski, Ph.D.

Biomedical Engineer

ODE/DNPMD/NSDB

WO 66, Rm 2656

10903 New Hampshire Avenue

Silver Spring, MD 20993

(240) 402-6032

Stacie.Gutowski@fda.hhs.gov<mailto:Stacie.Gutowski@fda.hhs.gov>

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From: Gutowski, Stacie
Sent: Monday, March 07, 2016 2:17 PM
To: 'Kim Schmelzer'
Cc: k151790@docs.fda.gov
Subject: RE: K151790/S001 Question

Dear Ms. Schmelzer,

(b)(4)

(b)(4) Please let me know if you have any further questions regarding this information.

Sincerely,
Stacie Gutowski, Ph.D.
Biomedical Engineer
ODE/DNPMD/NSDB
WO 66, Rm 2656
10903 New Hampshire Avenue
Silver Spring, MD 20993
(240) 402-6032
Stacie.Gutowski@fda.hhs.gov

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From: Kim Schmelzer [mailto:(b)(6)
Sent: Wednesday, March 02, 2016 2:51 PM
To: Gutowski, Stacie
Subject: RE: K151790/S001 Question

Stacie,

I hope this email finds you well.

(b)(4)

Thank you,
Kim Schmelzer | Quality Manager
PMT Corporation | Permark
1500 Park Road Chanhassen MN 55317 USA
D: +952.470.0866 | F: +952.470.0865
www.pmtcorp.com | www.permark.com

Description: pmt_logo

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

Hello Kim,

(b)(4)

Stacie Gutowski, Ph.D.
Biomedical Engineer
ODE/DNPMD/NSDB
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Stacie - Thanks for working with Kim and myself on this 510(k) application.

(b)(4)

Thanks,

- Ben

Benjamin Osa

Neurosurgery Engineering Manager

PMT Corporation

1500 Park Road

Chanhassen, MN 55317

Email: <mailto:(b)(6)

(P) 952-470-0866

(F) 952-470-0865

From: Gutowski, Stacie [mailto:Stacie.Gutowski@fda.hhs.gov]
Sent: Wednesday, June 15, 2016 8:01 PM
To: Ben Osa
Cc: k151790@docs.fda.gov; (b)(6)
Subject: RE: FDA requesting teleconference with your team

Hello Ben,

Thank you for understanding. The call-in information is below. We look forward to speaking with you at 2pm (eastern) on June 16.

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

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Stacie Gutowski, Ph.D.

Biomedical Engineer

ODE/DNPMD/NSDB

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From: Ben Osa [mailto:(b)(6)

Sent: Wednesday, June 15, 2016 5:29 PM

To: Gutowski, Stacie

Cc: k151790@docs.fda.gov; (b)(6)

Subject: RE: FDA requesting teleconference with your team

Hi Stacie - We can do a conference call tomorrow. Is there a dial in # for the call?

(b)(4)

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

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Thanks for your help on this submittal.

- Ben

Benjamin Osa

Neurosurgery Engineering Manager

PMT Corporation

1500 Park Road

Chanhassen, MN 55317

Email: (b)(6)

(P) 952-470-0866

(F) 952-470-0865

From: Gutowski, Stacie [mailto:Stacie.Gutowski@fda.hhs.gov]

Sent: Wednesday, June 15, 2016 3:58 PM

To: Ben Osa

Cc: k151790@docs.fda.gov; (b)(6)

Subject: RE: FDA requesting teleconference with your team

Hello Ben,

(b)(4)

Stacie Gutowski, Ph.D.

Biomedical Engineer

ODE/DNPMD/NSDB

WO 66, Rm 2656

10903 New Hampshire Avenue

Silver Spring, MD 20993

(240) 402-6032

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Cc: k151790@docs.fda.gov; (b)(6)
Subject: FDA requesting teleconference with your team

Hi Stacie - (b)(6)
(b)(6)

Is there a way we can do a teleconference on that date or a day soon afterwards?

Please let me know.

Thanks,

- Ben

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Sent: Wednesday, June 15, 2016 1:47 PM

To: Kim Schmelzer

Cc: k151790@docs.fda.gov

Subject: FDA requesting teleconference with your team

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(b)(4) Can we setup a teleconference meeting with you and your team tomorrow afternoon at 2pm (eastern time)? Please let me know if you are available.

Sincerely,

Stacie Gutowski, Ph.D.

Biomedical Engineer

ODE/DNPMD/NSDB

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Document type: TECHNICAL REPORT	Document No. (b)(4)	Page 1 of 7
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Dear Ms. Schmelzer,

Thank you for following up with the requested information. (b)(4)

(b)(4)

Please let me know if you have any questions.

Stacie Gutowski, Ph.D.

Biomedical Engineer

ODE/DNPMD/NSDB

WO 66, Rm 2656

10903 New Hampshire Avenue

Silver Spring, MD 20993

(240) 402-6032

Stacie.Gutowski@fda.hhs.gov<mailto:Stacie.Gutowski@fda.hhs.gov>

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From: Kim Schmelzer [mailto: (b)(6)

Sent: Wednesday, October 14, 2015 2:15 PM

To: Gutowski, Stacie

Cc: k151790@docs.fda.gov

Subject: RE: K151790/S001 Follow-up Information Request

Stacie,

Thank you for your prompt reviewed and response. It is greatly appreciated.

(b)(4)

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

Let me know if you have any questions or need clarification.

Thank you,

Kim Schmelzer | Quality Manager

PMT Corporation | Permark

1500 Park Road Chanhassen MN 55317 USA

D: +952.470.0866 | F: +952.470.0865

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From: Gutowski, Stacie [mailto:Stacie.Gutowski@fda.hhs.gov]

Sent: Wednesday, October 14, 2015 11:38 AM

To: (b)(6) <mailto: (b)(6)

Cc: k151790@docs.fda.gov<mailto:k151790@docs.fda.gov>

Subject: K151790/S001 Follow-up Information Request

Ms. Schmelzer,

We have completed administrative review of your submission (K151790) and have accepted the file for substantive review. (b)(4)

(b)(4)

(b)(4) Please email me with the updated documents, and be sure to cc the docs.fda.gov email address above on all future communications for this file. You only need to send the documentation for the items requested, no need to send the whole submission again.

Please let me know if you have any questions.

Stacie Gutowski, Ph.D.

Biomedical Engineer

ODE/DNPMD/NSDB

WO 66, Rm 2656

10903 New Hampshire Avenue

Silver Spring, MD 20993

(240) 402-6032

Stacie.Gutowski@fda.hhs.gov<mailto:Stacie.Gutowski@fda.hhs.gov>

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From: Stacie Gutowski [mailto:stacie.gutowski@fda.hhs.gov]

Records processed under FOIA Request 2024-2207; Released by CDRH on 11-13-2024

Sent: Wednesday, October 14, 2015 11:50 AM

To: (b)(6) <mailto: (b)(6)

Cc: Gutowski, Stacie

Subject: K151790/S001 was Accepted

October 14, 2015

Acceptance Review Notification - Accepted

An administrative acceptance review was conducted on your premarket notification (510(k)) K151790/S001, and it was found to contain all of the necessary elements and information needed to proceed with the substantive review. We will contact you should we require any additional information during the course of the substantive review. The lead reviewer assigned to your submission is Stacie Gutowski.

*** This is a system-generated email notification ***

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May 20, 2014

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Freedom of Information Act Request 2018-4207 Released by CDRH on July 11, 2021

Memorandum

Biocompatibility Review

Date:	June 29, 2016
To:	Stacie Gutowski, Ph.D., Lead Reviewer DNPMD/NSDB
From:	Dhanya Williams, M.S. Biologist/Scientific Reviewer, DNPMD/NNDB
Reviewer Electronic Signature:	
Subject:	K151790/S002
Applicant:	PMT Corporation 1500 Park Road Chanhassen, MN 55317
Device (Trade name):	PMT Platinum Depthalon® Depth Electrodes
Device (Regulation name):	Depth Electrode
Contact:	Kim Schmelzer, Quality Manager PMT Corporation 1500 Park Road Chanhassen, MN 55317 Phone: 952-470-0866 Fax: 952-470-0865 Email: (b)(6)
Recommendation:	**Substantially Equivalent (SESE)**

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Document title: (b)(4)	Effective Date 11/24/04	Current Rev. (b)(4)

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May 19, 2014

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From: Williams, Dhanya K

Sent: Friday, July 08, 2016 4:01 PM

To: Gutowski, Stacie

Cc: Williams, Dhanya K

Subject: RE: (b)(5) needed for K151790

Hi Stacie,

(b)(5)

Thanks!

Dhanya

From: Gutowski, Stacie

Sent: Friday, July 08, 2016 3:22 PM

To: Williams, Dhanya K

Subject: FW: (b)(5) needed for K151790

Hi Dhanya,

(b)(5)

-Stacie

From: Kim Schmelzer [mailto:(b)(6)

Sent: Friday, July 08, 2016 3:17 PM

To: Gutowski, Stacie

Subject: RE: (b)(4) needed for K151790

Stacie,

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

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(b)(4)

Thank you,

Kim Schmelzer | Quality Manager

PMT Corporation | Permark

1500 Park Road Chanhassen MN 55317 USA

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From: Gutowski, Stacie [mailto:Stacie.Gutowski@fda.hhs.gov]

Sent: Friday, July 08, 2016 2:15 PM

To: Kim Schmelzer

Cc: k151790@docs.fda.gov<mailto:k151790@docs.fda.gov>

Subject: RE: (b)(4) needed for K151790

Hi Kim,

(b)(4)

Stacie Gutowski, Ph.D.

Biomedical Engineer

ODE/DNPMD/NSDB

WO 66, Rm 2656

10903 New Hampshire Avenue

Silver Spring, MD 20993

(240) 402-6032

Stacie.Gutowski@fda.hhs.gov<mailto:Stacie.Gutowski@fda.hhs.gov>

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https://www.research.net/s/cdrhcustomerservice?O=400&D=460&B=462&E=&S=E

From: Kim Schmelzer [mailto:(b)(6)

Sent: Thursday, July 07, 2016 9:54 AM

To: Gutowski, Stacie

Subject: RE: (b)(4) needed for K151790

Stacie,

(b)(4)

Thank you,

Kim Schmelzer | Quality Manager

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From: Gutowski, Stacie [mailto:Stacie.Gutowski@fda.hhs.gov]

Sent: Thursday, July 07, 2016 6:42 AM

To: Kim Schmelzer

Cc: k151790@docs.fda.gov<mailto:k151790@docs.fda.gov>

Subject: RE: (b)(4) needed for K151790

Hi Kim,

(b)(4)

Stacie Gutowski, Ph.D.

Biomedical Engineer

ODE/DNPMD/NSDB

WO 66, Rm 2656

10903 New Hampshire Avenue

Silver Spring, MD 20993

(240) 402-6032

Stacie.Gutowski@fda.hhs.gov<mailto:Stacie.Gutowski@fda.hhs.gov>

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From: Kim Schmelzer [mailto:(b)(6)]

Sent: Wednesday, July 06, 2016 4:55 PM

To: Gutowski, Stacie

Cc: (b)(6) <mailto:(b)(6)>

Subject: RE: (b)(4) needed for K151790

Stacie,

Regarding you first question;

(b)(4)

Let me know if you have any further questions on this.

Thank you,

Kim Schmelzer | Quality Manager

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From: Gutowski, Stacie [mailto:Stacie.Gutowski@fda.hhs.gov]

Sent: Wednesday, July 06, 2016 12:20 PM

To: Kim Schmelzer

Subject: RE: (b)(4) needed for K151790

Hello Kim,

(b)(4)

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(b)(4)

Stacie Gutowski, Ph.D.

Biomedical Engineer

ODE/DNPMD/NSDB

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From: Kim Schmelzer [mailto:(b)(6)

Sent: Wednesday, July 06, 2016 12:05 PM

To: Gutowski, Stacie

Subject: RE: (b)(4) needed for K151790

Stacie,

(b)(4)

Thank you,

Kim Schmelzer | Quality Manager

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From: Gutowski, Stacie [mailto:Stacie.Gutowski@fda.hhs.gov]

Sent: Wednesday, July 06, 2016 10:12 AM

To: Kim Schmelzer

Cc: k151790@docs.fda.gov<mailto:k151790@docs.fda.gov>

Subject: (b)(4) needed for K151790

Hello Kim,

(b)(4)

Stacie Gutowski, Ph.D.

Biomedical Engineer

ODE/DNPMD/NSDB

WO 66, Rm 2656

10903 New Hampshire Avenue

Silver Spring, MD 20993

(240) 402-6032

Stacie.Gutowski@fda.hhs.gov<mailto:Stacie.Gutowski@fda.hhs.gov>

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1500 Park Road
Chanhassen, MN 55317

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Hi Kim,

(b)(4)

Stacie Gutowski, Ph.D.

Biomedical Engineer

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To: Gutowski, Stacie

Cc: (b)(6)

Subject: RE: (b)(4) needed for K151790

Stacie,

(b)(4)

Let me know if you have any further questions on this.

Thank you,

Kim Schmelzer | Quality Manager

PMT Corporation | Permark

1500 Park Road Chanhassen MN 55317 USA

D: +952.470.0866 | F: +952.470.0865

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From: Gutowski, Stacie [mailto:Stacie.Gutowski@fda.hhs.gov]

Sent: Wednesday, July 06, 2016 12:20 PM

To: Kim Schmelzer

Subject: RE: (b)(4) needed for K151790

Hello Kim,

(b)(4)

Stacie Gutowski, Ph.D.

Biomedical Engineer

ODE/DNPMD/NSDB

WO 66, Rm 2656

10903 New Hampshire Avenue

Silver Spring, MD 20993

(240) 402-6032

Stacie.Gutowski@fda.hhs.gov<mailto:Stacie.Gutowski@fda.hhs.gov>

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From: Kim Schmelzer [mailto: (b)(6)

Sent: Wednesday, July 06, 2016 12:05 PM

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To: Gutowski, Stacie

Subject: RE: (b)(4) needed for K151790

Stacie,

(b)(4) What further information do you need?

Thank you,

Kim Schmelzer | Quality Manager

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From: Gutowski, Stacie [mailto:Stacie.Gutowski@fda.hhs.gov]

Sent: Wednesday, July 06, 2016 10:12 AM

To: Kim Schmelzer

Cc: k151790@docs.fda.gov<mailto:k151790@docs.fda.gov>

Subject: (b)(4) needed for K151790

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Stacie Gutowski, Ph.D.

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(b)(4)

PMT CORPORATION

Platinum Depthalon Depth Electrode

(b)(4)

(b)(4)

May 20, 2014

(b)(4)

(b)(4)

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From: Kim Schmelzer [mailto: (b)(6)

Sent: Wednesday, June 22, 2016 4:54 PM

To: Gutowski, Stacie

Cc: (b)(6)

Subject: Follow-up deficiency information for K151790 - Email #2

June 22, 2016

U.S. Food and Drug Administration

Center for Devices and Radiological Health

Document Control Center - WO66-G609

10903 New Hampshire Avenue

Silver Spring, MD 20993-0002

RE: K157190/S002

Device Name: PMT Platinum Depthalon(r) Depth Electrodes

Stacie Gutowski, Ph.D.,

The attached information located in this email is in response to your email received at PMT Corporation on Monday June 20, 2016 regarding the premarket 510(k) notification for PMT(r) Platinum Depthalon(r) Depth Electrodes. (b)(4) (b)(4) The responses will be sent in multiple emails. Should you have any questions please contact me.

Sincerely,

Thank you,

Kim Schmelzer | Quality Manager

PMT Corporation | Permark

1500 Park Road Chanhassen MN 55317 USA

D: +952.470.0866 | F: +952.470.0865

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Public Health Service

Food and Drug Administration
Office Location
Business Address
Phone Number

Premarket Notification [510(k)] Review

Post-Review Reminders

- ☐ Final Check: Ensure your documentation accurately reflects the final recommendation prior to signature (e.g., Review Summary, data in the Device Description section, the Labeling section, etc)
- ☐ Complete CTS: Procode, Clinical Trials, Combo Product, MR compatibility
- ☐ Ensure the content of the 510(k) Summary is accurate (N/A if a 510(k) Statement was provided instead).
- ☐ For SE Decisions: Upload SE Letter, and PDFs of IFU form and 510(k) Summary (if included) in DocMan.

To add reminders, type the reminder in the text field to the left then press the Tab key.

Date: December 4, 2015

Reviewer: Stacie Gutowski, Ph.D.

Subject: Traditional 510(k)# K157190

Applicant: PMT Corporation

Device Trade Name: Depthalon Depth Electrode

Contact Name: Kim Schmelzer

Contact Title: Quality Manager

Correspondent Firm:

Phone: 952-470-0866 **Email:** (b)(6)

Received Date: October 9, 2015

Due Date: December 8, 2015

Reg #: 882.1330 **Reg Name:** Depth Electrode

Class: II **Product Code(s):** GZL

Predicate Devices:

Submission #	Pro Code	Device Trade Name	Owner
K802152	GZL	PMT Depthalon Depth #2102	Progress Mankind Technology
K041604	GZL	Macro-micro Depth Electrode	Ad-tech Medical Instrument Corp.

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

Records processed under FOIA Request 2024-2207; Released by CDRH on 11-13-2024

(b)(5)

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

Records processed under FOIA Request 2024-2207; Released by CDRH on 11-13-2024

(b)(5)

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

Records processed under FOIA Request 2024-2207; Released by CDRH on 11-13-2024

(b)(5)

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

Records processed under FOIA Request 2024-2207; Released by CDRH on 11-13-2024

(b)(5)

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

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(b)(5)

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Records processed under FOIA Request 2024-2207; Released by CDRH on 11-13-2024

(b)(5)

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

Hello Ben,
Thank you for understanding. The call-in information is below. We look forward to speaking with you at 2pm (eastern) on June 16.

(b)(4)

Stacie Gutowski, Ph.D.
Biomedical Engineer
ODE/DNPMD/NSDB
WO 66, Rm 2656
10903 New Hampshire Avenue
Silver Spring, MD 20993
(240) 402-6032
Stacie.Gutowski@fda.hhs.gov

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https://www.research.net/s/cdrhcustomerservice?O=400&D=460&B=462&E=&S=E

From: Ben Osa [mailto:(b)(6)]
Sent: Wednesday, June 15, 2016 5:29 PM
To: Gutowski, Stacie
Cc: k151790@docs.fda.gov; (b)(6)
Subject: RE: FDA requesting teleconference with your team

Hi Stacie – We can do a conference call tomorrow. Is there a dial in # for the call?

(b)(4)

Thanks for your help on this submittal.

- Ben

Benjamin Osa
Neurosurgery Engineering Manager
PMT Corporation
1500 Park Road
Chanhassen, MN 55317
Email: (b)(6)
(P) 952-470-0866
(F) 952-470-0865

From: Gutowski, Stacie [mailto:Stacie.Gutowski@fda.hhs.gov]
Sent: Wednesday, June 15, 2016 3:58 PM
To: Ben Osa
Cc: k151790@docs.fda.gov; (b)(6)
Subject: RE: FDA requesting teleconference with your team

Hello Ben,

(b)(4)

Stacie Gutowski, Ph.D.
Biomedical Engineer
ODE/DNPMD/NSDB
WO 66, Rm 2656
10903 New Hampshire Avenue
Silver Spring, MD 20993
(240) 402-6032
Stacie.Gutowski@fda.hhs.gov

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https://www.research.net/s/cdrhcustomerservice?O=400&D=460&B=462&E=&S=E

From: Ben Osa [mailto:(b)(6)]
Sent: Wednesday, June 15, 2016 4:52 PM
To: Gutowski, Stacie

Records processed under FOIA Request 2024-2207; Released by CDRH on 11-13-2024

Cc: k151790@docs.fda.gov; (b)(6)
Subject: FDA requesting teleconference with your team

Hi Stacie – (b)(6)

Is there a way we can do a teleconference on that date or a day soon afterwards?

Please let me know.

Thanks,

- Ben

Benjamin Osa
Neurosurgery Engineering Manager
PMT Corporation
1500 Park Road
Chanhassen, MN 55317
Email (b)(6)
(P) 952-470-0866
(F) 952-470-0865

From: Gutowski, Stacie [mailto:Stacie.Gutowski@fda.hhs.gov]
Sent: Wednesday, June 15, 2016 1:47 PM
To: Kim Schmelzer
Cc: k151790@docs.fda.gov
Subject: FDA requesting teleconference with your team

Hello Kim,
(b)(4) Can we setup a teleconference meeting with you and your team tomorrow afternoon at 2pm (eastern time)? Please let me know if you are available.

Sincerely,
Stacie Gutowski, Ph.D.
Biomedical Engineer
ODE/DNPMD/NSDB
WO 66, Rm 2656
10903 New Hampshire Avenue
Silver Spring, MD 20993
(240) 402-6032
Stacie.Gutowski@fda.hhs.gov

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https://www.research.net/s/cdrhcustomerservice?O=400&D=460&B=462&E=&S=E

Records processed under FOIA Request 2024-2207; Released by CDRH on 11-13-2024

From: Kim Schmelzer [mailto: (b)(6)
Sent: Wednesday, June 22, 2016 4:54 PM
To: Gutowski, Stacie
Cc: (b)(6)
Subject: Follow-up deficiency information for K151790 - Email #2

June 22, 2016

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

RE: K157190/S002
Device Name: PMT Platinum Depthalon® Depth Electrodes

Stacie Gutowski, Ph.D.,

The attached information located in this email is in response to your email received at PMT Corporation on Monday June 20, 2016 regarding the premarket 510(k) notification for PMT® Platinum Depthalon® Depth Electrodes. (b)(4) The responses will be sent in multiple emails. Should you have any questions please contact me.

Sincerely,
Thank you,
Kim Schmelzer | Quality Manager
PMT Corporation | Permark
1500 Park Road Chanhassen MN 55317 USA
D: +952.470.0866 | F: +952.470.0865
www.pmtcorp.com | www.permark.com

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

Dear Ms. Schmelzer,
Please find our responses to your questions below.

(b)(4)

Sincerely,
Stacie Gutowski, Ph.D.
Biomedical Engineer
ODE/DNPMD/NSDB
WO 66, Rm 2656
10903 New Hampshire Avenue
Silver Spring, MD 20993
(240) 402-6032
Stacie.Gutowski@fda.hhs.gov

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https://www.research.net/s/cdrhcustomerservice?O=400&D=460&B=462&E=&S=E

Records processed under FOIA Request 2024-2207; Released by CDRH on 11-13-2024

From: Kim Schmelzer [mailto (b)(6)
Sent: Monday, March 07, 2016 3:32 PM
To: Gutowski, Stacie
Subject: RE: K151790/S001 Question
Importance: High

Stacie,

Thank you for your reply. (b)(4)

(b)(4)

Thank you,
Kim Schmelzer | Quality Manager
PMT Corporation | Permark
1500 Park Road Chanhassen MN 55317 USA
D: +952.470.0866 | F: +952.470.0865
www.pmtcorp.com | www.permark.com

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From: Gutowski, Stacie [mailto:Stacie.Gutowski@fda.hhs.gov]
Sent: Monday, March 07, 2016 1:17 PM
To: Kim Schmelzer
Cc: k151790@docs.fda.gov
Subject: RE: K151790/S001 Question

Dear Ms. Schmelzer,

(b)(4)

(b)(4) Please let me know if you have any further questions regarding this information.

Sincerely,
Stacie Gutowski, Ph.D.
Biomedical Engineer
ODE/DNPMD/NSDB
WO 66, Rm 2656
10903 New Hampshire Avenue
Silver Spring, MD 20993
(240) 402-6032
Stacie.Gutowski@fda.hhs.gov

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received:
https://www.research.net/s/cdrhcustomerservice?O=400&D=460&B=462&E=&S=E

From: Kim Schmelzer [mailto (b)(6)
Sent: Wednesday, March 02, 2016 2:51 PM
To: Gutowski, Stacie
Subject: RE: K151790/S001 Question

Stacie,

I hope this email finds you well.

(b)(4)

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

Records processed under FOIA Request 2024-2207; Released by CDRH on 11-13-2024

(b)(4)

Thank you,

Kim Schmelzer | Quality Manager
PMT Corporation | Permark
1500 Park Road Chanhassen MN 55317 USA
D: +952.470.0866 | F: +952.470.0865
www.pmtcorp.com | www.permark.com

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

Records processed under FOIA Request 2024-2207; Released by CDRH on 11-13-2024

From: Kim Schmelzer [mailto: (b)(6)
Sent: Wednesday, June 22, 2016 4:52 PM
To: Gutowski, Stacie
Cc: (b)(6)
Subject: Follow-up deficiency information for K151790 - Email #1

June 22, 2016

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

RE: K157190/S002
Device Name: PMT Platinum Depthalon® Depth Electrodes

Stacie Gutowski, Ph.D.,

The attached information located in this email is in response to your email received at PMT Corporation on Monday June 20, 2016 regarding the premarket 510(k) notification for PMT® Platinum Depthalon® Depth Electrodes. (b)(4) The responses will be sent in multiple emails. Should you have any questions please contact me.

Sincerely,
Thank you,
Kim Schmelzer | Quality Manager
PMT Corporation | Permark
1500 Park Road Chanhassen MN 55317 USA
D: +952.470.0866 | F: +952.470.0865
www.pmtcorp.com | www.permark.com

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

Records processed under FOIA Request 2024-2207; Released by CDRH on 11-13-2024

From: Kim Schmelzer [mailto:(b)(6)

Sent: Monday, October 19, 2015 5:04 PM

To: Gutowski, Stacie

Subject: RE: K151790/S001 Follow-up Information Request

Staci,

I hope you had a good weekend!

(b)(4)

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

Records processed under FOIA Request 2024-2207; Released by CDRH on 11-13-2024

(b)(4)

Let me know if you have any further questions or concerns.

Thank you,

Kim Schmelzer | Quality Manager

PMT Corporation | Permark

1500 Park Road Chanhassen MN 55317 USA

D: +952.470.0866 | F: +952.470.0865

Toll Free: 1.800.MANKIND (626-5463)

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From: Gutowski, Stacie [mailto:Stacie.Gutowski@fda.hhs.gov]

Sent: Friday, October 16, 2015 7:56 AM

To: Kim Schmelzer

Cc: k151790@docs.fda.gov<mailto:k151790@docs.fda.gov>

Subject: RE: K151790/S001 Follow-up Information Request

Dear Ms. Schmelzer,

Thank you for following up with the requested information. (b)(4)

(b)(4)

Please let me know if you have any questions.

Stacie Gutowski, Ph.D.

Biomedical Engineer

ODE/DNPMD/NSDB

WO 66, Rm 2656

10903 New Hampshire Avenue

Silver Spring, MD 20993

Records processed under FOIA Request 2024-2207; Released by CDRH on 11-13-2024

(240) 402-6032

Stacie.Gutowski@fda.hhs.gov<mailto:Stacie.Gutowski@fda.hhs.gov>

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https://www.research.net/s/cdrhcustomerservice?O=400&D=460&B=462&E=&S=E

From: Kim Schmelzer [mailto:(b)(6)

Sent: Wednesday, October 14, 2015 2:15 PM

To: Gutowski, Stacie

Cc: k151790@docs.fda.gov<mailto:k151790@docs.fda.gov>

Subject: RE: K151790/S001 Follow-up Information Request

Stacie,

(b)(4)

Let me know if you have any questions or need clarification.

Thank you,

Kim Schmelzer | Quality Manager

PMT Corporation | Permark

1500 Park Road Chanhassen MN 55317 USA

D: +952.470.0866 | F: +952.470.0865

Toll Free: 1.800.MANKIND (626-5463)

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all copies of this communication, including all attachments.

From: Gutowski, Stacie [mailto:Stacie.Gutowski@fda.hhs.gov]

Sent: Wednesday, October 14, 2015 11:38 AM

To: (b)(6) <mailto: (b)(6) >

Cc: k151790@docs.fda.gov<mailto:k151790@docs.fda.gov>

Subject: K151790/S001 Follow-up Information Request

Ms. Schmelzer,

We have completed administrative review of your submission (K151790) and have accepted the file for substantive review. (b)(4)

(b)(4)

(b)(4) Please email me with the updated documents, and be sure to cc the docs.fda.gov email address above on all future communications for this file. You only need to send the documentation for the items requested, no need to send the whole submission again.

Please let me know if you have any questions.

Stacie Gutowski, Ph.D.

Biomedical Engineer

ODE/DNPMD/NSDB

WO 66, Rm 2656

10903 New Hampshire Avenue

Silver Spring, MD 20993

(240) 402-6032

Stacie.Gutowski@fda.hhs.gov<mailto:Stacie.Gutowski@fda.hhs.gov>

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https://www.research.net/s/cdrhcustomerservice?O=400&D=460&B=462&E=&S=E

From: Stacie Gutowski [mailto:stacie.gutowski@fda.hhs.gov]

Sent: Wednesday, October 14, 2015 11:50 AM

To: (b)(6) <mailto: (b)(6) >

Cc: Gutowski, Stacie

Subject: K151790/S001 was Accepted

October 14, 2015

Acceptance Review Notification - Accepted

An administrative acceptance review was conducted on your premarket notification (510(k)) K151790/S001, and it was found to contain all of the necessary elements and information needed to proceed with the substantive review. We will contact you should we require any additional information during the course of the substantive review. The lead reviewer assigned to your submission is Stacie Gutowski.

*** This is a system-generated email notification ***

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

Records processed under FOIA Request 2024-2207; Released by CDRH on 11-13-2024

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

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

(b)(4)

Dear Ms. Schmelzer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in

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

Records processed under FOIA Request 2024-2207; Released by CDRH on 11-13-2024

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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

Sincerely yours,

Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

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

Hello Kim,

(b)(4) Can we setup a teleconference meeting with you and your team tomorrow afternoon at 2pm (eastern time)? Please let me know if you are available.

Sincerely,
Stacie Gutowski, Ph.D.
Biomedical Engineer
ODE/DNPMD/NSDB
WO 66, Rm 2656
10903 New Hampshire Avenue
Silver Spring, MD 20993
(240) 402-6032
Stacie.Gutowski@fda.hhs.gov

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(b)(4)

Records processed under FOIA Request 2024-2207; Released by CDRH on 11-13-2024

(b)(4)

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

Records processed under FOIA Request 2024-2207; Released by CDRH on 11-13-2024

(b)(4)

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

Records processed under FOIA Request 2024-2207; Released by CDRH on 11-13-2024

(b)(4)

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

Records processed under FOIA Request 2024-2207; Released by CDRH on 11-13-2024

(b)(4)

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

Records processed under FOIA Request 2024-2207; Released by CDRH on 11-13-2024

(b)(4)

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

Records processed under FOIA Request 2024-2207; Released by CDRH on 11-13-2024

From: Kim Schmelzer [mailto: (b)(6)

Sent: Wednesday, June 22, 2016 4:55 PM

To: Gutowski, Stacie

Cc: (b)(6)

Subject: FW: Follow-up deficiency information for K151790 - Email #3 Final

June 22, 2016

U.S. Food and Drug Administration

Center for Devices and Radiological Health

Document Control Center - WO66-G609

10903 New Hampshire Avenue

Silver Spring, MD 20993-0002

RE: K157190/S002

Device Name: PMT Platinum Depthalon(r) Depth Electrodes

Stacie Gutowski, Ph.D.,

The attached information located in this email is in response to your email received at PMT Corporation on Monday June 20, 2016 regarding the premarket 510(k) notification for PMT(r) Platinum Depthalon(r) Depth Electrodes. (b)(4) (b)(4) The responses will be sent in multiple emails. Should you have any questions please contact me.

Sincerely,

Thank you,

Kim Schmelzer | Quality Manager

PMT Corporation | Permark

1500 Park Road Chanhassen MN 55317 USA

D: +952.470.0866 | F: +952.470.0865

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Records processed under FOIA Request 2024-2207; Released by CDRH on 11-13-2024

October 14, 2015</br></br>

Acceptance Review Notification - Accepted

An administrative acceptance review was conducted on your premarket notification (510(k)) K151790/S001, and it was found to contain all of the necessary elements and information needed to proceed with the substantive review. We will contact you should we require any additional information during the course of the substantive review. The lead reviewer assigned to your submission is Stacie Gutowski.

 *** This is a system-generated email notification ***

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

Records processed under FOIA Request 2024-2207; Released by CDRH on 11-13-2024

July 31, 2015</br></br>

Acceptance Review Notification - Refuse To Accept (RTA)

We have completed the administrative acceptance review of your premarket notification (510(k)) submission K151790. Our review indicates that your 510(k) submission does not meet the criteria established for administrative completeness. Thus, we regret to inform you that we are unable to conduct a substantive review of your submission at this time and are placing it on RTA hold.

Please submit two copies of your response (1 eCopy and 1 paper copy), referencing the 510(k) number K151790, addressing the elements identified as missing or inconsistent in the attached checklist to:

U.S. Food and Drug Administration

Center for Devices and Radiological Heath

Document Control Center - WO66-G609

10903 New Hampshire Avenue

Silver Spring, MD 20993-0002

FDA will permit your 510(k) submission to remain on hold for a maximum of 180 days from the date of this email. If you do not correct the missing or inconsistent elements identified in the checklist within 180 days, we will consider this 510(k) submission to be withdrawn, and we will delete it from our review system.

Upon receipt of the requested information, FDA will conduct another administrative review of your 510(k) submission.

Should you have questions about this email, you may contact Stacie Gutowski, the lead reviewer assigned to your 510(k) submission.

For additional information regarding the Refuse to Accept Policy for 510(k)s please refer to the guidance document available at http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM315014.pdf.

 *** This is a system-generated email notification ***

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

Records processed under FOIA Request 2024-2207; Released by CDRH on 11-13-2024

K151790/S002

PMT®

1500 Park Road • Chanhassen, MN 55317 USA • Phone (952) 470-0866 • Fax (952) 470-0865 • www.pmtcorp.com

June 2, 2016

FDA/CDRH/DCC
JUN 09 2016
RECEIVED

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

Reference: K151790/S002 – PMT® Platinum Depthalon® Depth Electrode (b)(4)

To Whom It May Concern:

Per your email request PMT hereby submits this replacement eCopy for the Platinum Depthalon Depth Electrode product family 510(k) submittal K151790/S002.

This submission contains confidential commercial and trade secret information. We respectfully request that you give this notification the maximum protection provided by law.

Thank you in advance for your consideration of this application. If there are any questions, please contact me at 952-470-0866 or (b)(6)

Sincerely,

(b)(6)

Kim Schmelzer (b)(6)
Quality Manager
PMT Corporation

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

K151790/S002

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PMT® Corporation
1500 PARK ROAD · CHANHASSEN, MN 55317 USA · PHONE (952) 470-0866 · 1-800-MANKIND · FAX (952) 470-0865

May 10, 2016

FDA/CDRH/DCC
MAY 31 2016
RECEIVED

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

RE: K157190/S001
Device Name: PMT Platinum Depthalon® Depth Electrodes

Stacie Gutowski, Ph.D.,

The enclosed information is in response to your fax received at PMT Corporation on Monday December 7, 2015 regarding the premarket 510(k) notification for PMT® Platinum Depthalon® Depth Electrodes. Should you have any questions please contact me.

Sincerely,

(b)(6)

Kim Schmelzer
Quality Manager

(b)(6)

31

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

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From: Kim Schmelzer [mailto:(b)(6)
Sent: Wednesday, June 22, 2016 4:55 PM
To: Gutowski, Stacie
Cc: (b)(6)
Subject: FW: Follow-up deficiency information for K151790 - Email #3 Final

June 22, 2016

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

RE: K157190/S002
Device Name: PMT Platinum Depthalon® Depth Electrodes

Stacie Gutowski, Ph.D.,

The attached information located in this email is in response to your email received at PMT Corporation on Monday June 20, 2016 regarding the premarket 510(k) notification for PMT® Platinum Depthalon® Depth Electrodes. (b)(4) The responses will be sent in multiple emails. Should you have any questions please contact me.

Sincerely,
Thank you,
Kim Schmelzer | Quality Manager
PMT Corporation | Permark
1500 Park Road Chanhassen MN 55317 USA
D: +952.470.0866 | F: +952.470.0865
www.pmtcorp.com | www.permark.com

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

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Hi Stacie - (b)(6)

(b)(6)

Is there a way we can do a teleconference on that date or a day soon afterwards?

Please let me know.

Thanks,

- Ben

Benjamin Osa

Neurosurgery Engineering Manager

PMT Corporation

1500 Park Road

Chanhassen, MN 55317

Email: (b)(6)

(P) 952-470-0866

(F) 952-470-0865

From: Gutowski, Stacie [mailto:Stacie.Gutowski@fda.hhs.gov]
Sent: Wednesday, June 15, 2016 1:47 PM
To: Kim Schmelzer
Cc: k151790@docs.fda.gov
Subject: FDA requesting teleconference with your team

Hello Kim,

(b)(4)

(b)(4) Can we setup a teleconference meeting with you and your team tomorrow afternoon at 2pm (eastern time)? Please let me know if you are available.

Sincerely,

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

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Stacie Gutowski, Ph.D.

Biomedical Engineer

ODE/DNPMD/NSDB

WO 66, Rm 2656

10903 New Hampshire Avenue

Silver Spring, MD 20993

(240) 402-6032

Stacie.Gutowski@fda.hhs.gov

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&D=460&B=462&E=&S=E

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

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Hello Kim,

(b)(4)

Stacie Gutowski, Ph.D.
Biomedical Engineer
ODE/DNPMD/NSDB
WO 66, Rm 2656
10903 New Hampshire Avenue
Silver Spring, MD 20993
(240) 402-6032
Stacie.Gutowski@fda.hhs.gov

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From: Kim Schmelzer [mailto:(b)(6)
Sent: Wednesday, June 29, 2016 12:15 PM
To: Gutowski, Stacie
Cc: (b)(6)
Subject: Interactive Review for K151790

Stacie,

(b)(4)

I hope this answers your question. Please let me know if you have any further questions.

Thank you,
Kim Schmelzer | Quality Manager
PMT Corporation | Permark
1500 Park Road Chanhassen MN 55317 USA
D: +952.470.0866 | F: +952.470.0865
www.pmtcorp.com | www.permark.com

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1500 PARK ROAD · CHANHASSEN, MN 55317 USA · PHONE (952) 470-0866 · 1-800-MANKIND · FAX (952) 470-0865

(b)(4)

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

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PMT® Corporation

CE 0120

INSTRUCTION MANUAL

(b)(4)

Depthalon® Depth Electrode System

(b)(4)

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

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(b)(4)

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(b)(4)

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

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(b)(4)

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Records processed under FOIA Request 2024-2207; Released by CDRH on 11-13-2024

Dear Kim,

(b)(4)

Sincerely,

Stacie Gutowski, Ph.D.

Biomedical Engineer

ODE/DNPMD/NSDB

WO 66, Rm 2656

10903 New Hampshire Avenue

Silver Spring, MD 20993

(240) 402-6032

Stacie.Gutowski@fda.hhs.gov<mailto:Stacie.Gutowski@fda.hhs.gov>

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https://www.research.net/s/cdrhcustomerservice?O=400&D=460&B=462&E=&S=E

From: Kim Schmelzer [mailto: (b)(6)

Sent: Friday, December 04, 2015 2:17 PM

To: Gutowski, Stacie

Subject: RE: K151790/S001 Follow-up Information Request

Stacie,

Thank you again for your prompt response. (b)(4)
(b)(4)

Thank you,

Kim Schmelzer | Quality Manager

PMT Corporation | Permark

1500 Park Road Chanhassen MN 55317 USA

D: +952.470.0866 | F: +952.470.0865

Toll Free: 1.800.MANKIND (626-5463)

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From: Gutowski, Stacie [mailto:Stacie.Gutowski@fda.hhs.gov]

Sent: Friday, December 04, 2015 12:30 PM

To: Kim Schmelzer

Cc: k151790@docs.fda.gov<mailto:k151790@docs.fda.gov>

Subject: RE: K151790/S001 Follow-up Information Request

Dear Kim,

Thank you for your email. (b)(4) (b)(4) We are finalizing our review at this time and you should receive a more formal communication from us in the form of a letter within the next several business days.

Sincerely,

Stacie Gutowski, Ph.D.

Biomedical Engineer

ODE/DNPMD/NSDB

WO 66, Rm 2656

10903 New Hampshire Avenue

Silver Spring, MD 20993

(240) 402-6032

Stacie.Gutowski@fda.hhs.gov<mailto:Stacie.Gutowski@fda.hhs.gov>

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https://www.research.net/s/cdrhcustomerservice?O=400&D=460&B=462&E=&S=E

From: Kim Schmelzer [mailto:(b)(6)

Sent: Friday, December 04, 2015 1:17 PM

To: Gutowski, Stacie

Subject: RE: K151790/S001 Follow-up Information Request

Stacie,

I hope this email finds you well. (b)(4)

(b)(4)

Sincerley,

Kim Schmelzer | Quality Manager

PMT Corporation | Permark

1500 Park Road Chanhassen MN 55317 USA

D: +952.470.0866 | F: +952.470.0865

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From: Gutowski, Stacie [mailto:Stacie.Gutowski@fda.hhs.gov]

Sent: Monday, October 19, 2015 5:37 PM

To: Kim Schmelzer

Cc: k151790@docs.fda.gov<mailto:k151790@docs.fda.gov>

Subject: RE: K151790/S001 Follow-up Information Request

Dear Kim,

Thank you for the additional information. We will incorporate this into our review.

Sincerely,

Stacie Gutowski, Ph.D.

Biomedical Engineer

ODE/DNPMD/NSDB

WO 66, Rm 2656

10903 New Hampshire Avenue

Silver Spring, MD 20993

(240) 402-6032

Stacie.Gutowski@fda.hhs.gov<mailto:Stacie.Gutowski@fda.hhs.gov>

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https://www.research.net/s/cdrhcustomerservice?O=400&D=460&B=462&E=&S=E

From: Kim Schmelzer [mailto: (b)(6)

Sent: Monday, October 19, 2015 5:04 PM

To: Gutowski, Stacie

Subject: RE: K151790/S001 Follow-up Information Request

Staci,

I hope you had a good weekend!

(b)(4)

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

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(b)(4)

Let me know if you have any further questions or concerns.

Thank you,

Kim Schmelzer | Quality Manager

PMT Corporation | Permark

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From: Gutowski, Stacie [mailto:Stacie.Gutowski@fda.hhs.gov]

Sent: Friday, October 16, 2015 7:56 AM

To: Kim Schmelzer

Cc: k151790@docs.fda.gov<mailto:k151790@docs.fda.gov>

Subject: RE: K151790/S001 Follow-up Information Request

Dear Ms. Schmelzer,

Thank you for following up with the requested information. (b)(4)

(b)(4)

Please let me know if you have any questions.

Stacie Gutowski, Ph.D.

Biomedical Engineer

ODE/DNPMD/NSDB

WO 66, Rm 2656

10903 New Hampshire Avenue

Silver Spring, MD 20993

(240) 402-6032

Stacie.Gutowski@fda.hhs.gov<mailto:Stacie.Gutowski@fda.hhs.gov>

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https://www.research.net/s/cdrhcustomerservice?O=400&D=460&B=462&E=&S=E

From: Kim Schmelzer [mailto:(b)(6)

Sent: Wednesday, October 14, 2015 2:15 PM

To: Gutowski, Stacie

Cc: k151790@docs.fda.gov<mailto:k151790@docs.fda.gov>

Subject: RE: K151790/S001 Follow-up Information Request

Stacie,

(b)(4)

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

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(b)(4)

Let me know if you have any questions or need clarification.

Thank you,

Kim Schmelzer | Quality Manager

PMT Corporation | Permark

1500 Park Road Chanhassen MN 55317 USA

D: +952.470.0866 | F: +952.470.0865

Toll Free: 1.800.MANKIND (626-5463)

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From: Gutowski, Stacie [mailto:Stacie.Gutowski@fda.hhs.gov]

Sent: Wednesday, October 14, 2015 11:38 AM

To: (b)(6) <mailto:(b)(6)>

Cc: k151790@docs.fda.gov<mailto:k151790@docs.fda.gov>

Subject: K151790/S001 Follow-up Information Request

Ms. Schmelzer,

We have completed administrative review of your submission (K151790) and have accepted the file for substantive review. (b)(4)

(b)(4)

(b)(4) Please email me with the updated documents, and be sure to cc the docs.fda.gov email address above on all future communications for this file. You only need to send the documentation for the items requested, no need to send the whole submission again.

Please let me know if you have any questions.

Stacie Gutowski, Ph.D.

Biomedical Engineer

ODE/DNPMD/NSDB

WO 66, Rm 2656

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

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Stacie.Gutowski@fda.hhs.gov<mailto:Stacie.Gutowski@fda.hhs.gov>

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https://www.research.net/s/cdrhcustomerservice?O=400&D=460&B=462&E=&S=E

From: Stacie Gutowski [mailto:stacie.gutowski@fda.hhs.gov]

Sent: Wednesday, October 14, 2015 11:50 AM

To: (b)(6) <mailto: (b)(6) >

Cc: Gutowski, Stacie

Subject: K151790/S001 was Accepted

October 14, 2015

Acceptance Review Notification - Accepted

An administrative acceptance review was conducted on your premarket notification (510(k)) K151790/S001, and it was found to contain all of the necessary elements and information needed to proceed with the substantive review. We will contact you should we require any additional information during the course of the substantive review. The lead reviewer assigned to your submission is Stacie Gutowski.

*** This is a system-generated email notification ***

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

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PMT Corporation
510(k) Summary (b)(4)

Submitter's Name, Address, and Date of Submission

Kim Schmelzer
Quality Manager
PMT Corporation
1500 Park Road
Chanhassen, MN
Phone: 952-470-0866
Fax: 952-470-0865

Establishment Registration: 2182979

Submitted:

Device Name: Platinum Depthalon® Depth Electrodes

Trade Name: Depthalon® Depth Electrodes

Classification Name: 21 CFR 882.1330, Depth Electrode GZL

Classification: Class II

Common/Usual Name: Depth Electrode

Predicate Device: PMT Depthalon Depth Electrode – K802152
Ad-tech Corporation Macro-Micro Electrodes – K041604

Indication for Use:

(b)(4)

Device Description

The PMT Platinum Depthalon Depth Electrode is used intraoperatively for stimulating and monitoring recordable electrical brain activity or Electroencephalography (EEG) when less invasive methods do not provide the electrophysiology data necessary. This invasive intracranial, subdural electrode recording is performed through a burr hole leading into the brain. This method is necessary when the seizure focus is too small and / or too deep within the brain to produce a recordable EEG seizure.

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

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(b)(4)

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

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(b)(4)

SUBJECT: (b)(4)

(b)(4)

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

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(b)(4)

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Records processed under FOIA Request 2024-2207; Released by CDRH on 11-13-2024

Dear Ms. Schmelzer,

(b)(4)

Sincerely,
Stacie Gutowski, Ph.D.
Biomedical Engineer
ODE/DNPMD/NSDB
WO 66, Rm 2656
10903 New Hampshire Avenue
Silver Spring, MD 20993
(240) 402-6032
Stacie.Gutowski@fda.hhs.gov

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From: Kim Schmelzer [mailto: (b)(6)
Sent: Monday, March 14, 2016 5:05 PM
To: Gutowski, Stacie
Subject: RE: K151790/S001 Question
Importance: High

Stacie,

For the following;

(b)(4)

Thank you,
Kim Schmelzer | Quality Manager
PMT Corporation | Permark
1500 Park Road Chanhassen MN 55317 USA
D: +952.470.0866 | F: +952.470.0865
www.pmtcorp.com | www.permark.com

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From: Gutowski, Stacie [mailto:Stacie.Gutowski@fda.hhs.gov]
Sent: Wednesday, March 09, 2016 12:21 PM
To: Kim Schmelzer
Cc: k151790@docs.fda.gov
Subject: RE: K151790/S001 Question

Dear Ms. Schmelzer,
Please find our responses to your questions below.

(b)(4)

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

Records processed under FOIA Request 2024-2207; Released by CDRH on 11-13-2024

(b)(4)

Sincerely,
Stacie Gutowski, Ph.D.
Biomedical Engineer
ODE/DNPMD/NSDB
WO 66, Rm 2656
10903 New Hampshire Avenue
Silver Spring, MD 20993
(240) 402-6032
Stacie.Gutowski@fda.hhs.gov

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https://www.research.net/s/cdrhcustomerservice?O=400&D=460&B=462&E=&S=E

From: Kim Schmelzer [mailto: (b)(6)
Sent: Monday, March 07, 2016 3:32 PM
To: Gutowski, Stacie
Subject: RE: K151790/S001 Question
Importance: High

Stacie,

(b)(4)

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

Records processed under FOIA Request 2024-2207; Released by CDRH on 11-13-2024

(b)(4)

Thank you,
Kim Schmelzer | Quality Manager
PMT Corporation | Permark
1500 Park Road Chanhassen MN 55317 USA
D: +952.470.0866 | F: +952.470.0865
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From: Gutowski, Stacie [mailto:Stacie.Gutowski@fda.hhs.gov]
Sent: Monday, March 07, 2016 1:17 PM
To: Kim Schmelzer
Cc: k151790@docs.fda.gov
Subject: RE: K151790/S001 Question

Dear Ms. Schmelzer,
Thank you for your email! (b)(4)

(b)(4)

(b)(4) Please let me know if you have any further questions regarding this information.

Sincerely,
Stacie Gutowski, Ph.D.
Biomedical Engineer
ODE/DNPMD/NSDB
WO 66, Rm 2656
10903 New Hampshire Avenue
Silver Spring, MD 20993
(240) 402-6032
Stacie.Gutowski@fda.hhs.gov

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https://www.research.net/s/cdrhcustomerservice?O=400&D=460&B=462&E=&S=E

From: Kim Schmelzer [mailto: (b)(6)
Sent: Wednesday, March 02, 2016 2:51 PM
To: Gutowski, Stacie
Subject: RE: K151790/S001 Question

Stacie,

I hope this email finds you well.

(b)(4)

Thank you,
Kim Schmelzer | Quality Manager
PMT Corporation | Permark
1500 Park Road Chanhassen MN 55317 USA
D: +952.470.0866 | F: +952.470.0865
www.pmtcorp.com | www.permark.com

Description: pmt_logo

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Description of product packaging of the Depthalon Depth Electrodes

(b)(4)

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

Records processed under FOIA Request 2024-2207; Released by CDRH on 11-13-2024

(b)(4) Label

(b)(4)

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(b)(4) Label

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(b)(4) Label (b)(4)

(b)(4)

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(b)(4) Label (b)(4)

(b)(4)

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(b)(4) Label (b)(4)

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PMT® Corporation

CE 0120

INSTRUCTION MANUAL

(b)(4)

Depthalon® Depth Electrode System

(b)(4)

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Dear Ms. Schmelzer,

(b)(4)

Sincerely,

Stacie Gutowski, Ph.D.

Biomedical Engineer

ODE/DNPMD/NSDB

WO 66, Rm 2656

10903 New Hampshire Avenue

Silver Spring, MD 20993

(240) 402-6032

Stacie.Gutowski@fda.hhs.gov<mailto:Stacie.Gutowski@fda.hhs.gov>

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From: Kim Schmelzer [mailto:(b)(6)

Sent: Monday, March 14, 2016 5:05 PM

To: Gutowski, Stacie

Subject: RE: K151790/S001 Question

Importance: High

Stacie,

For the following;

(b)(4)

Thank you,

Kim Schmelzer | Quality Manager

PMT Corporation | Permark

1500 Park Road Chanhassen MN 55317 USA

D: +952.470.0866 | F: +952.470.0865

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

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From: Gutowski, Stacie [mailto:Stacie.Gutowski@fda.hhs.gov]

Sent: Wednesday, March 09, 2016 12:21 PM

To: Kim Schmelzer

Cc: k151790@docs.fda.gov<mailto:k151790@docs.fda.gov>

Subject: RE: K151790/S001 Question

Dear Ms. Schmelzer,

Please find our responses to your questions below.

(b)(4)

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

Records processed under FOIA Request 2024-2207, Released by CDRH on 11-13-2024

(b)(4)

Sincerely,

Stacie Gutowski, Ph.D.

Biomedical Engineer

ODE/DNPMD/NSDB

WO 66, Rm 2656

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

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Stacie.Gutowski@fda.hhs.gov<mailto:Stacie.Gutowski@fda.hhs.gov>

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From: Kim Schmelzer [mailto: (b)(6)

Sent: Monday, March 07, 2016 3:32 PM

To: Gutowski, Stacie

Subject: RE: K151790/S001 Question

Importance: High

Stacie,

(b)(4)

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

Records processed under FOIA Request 2024-2207; Released by CDRH on 11-13-2024

Thank you,

Kim Schmelzer | Quality Manager

PMT Corporation | Permark

1500 Park Road Chanhassen MN 55317 USA

D: +952.470.0866 | F: +952.470.0865

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From: Gutowski, Stacie [mailto:Stacie.Gutowski@fda.hhs.gov]

Sent: Monday, March 07, 2016 1:17 PM

To: Kim Schmelzer

Cc: k151790@docs.fda.gov<mailto:k151790@docs.fda.gov>

Subject: RE: K151790/S001 Question

Dear Ms. Schmelzer,

Thank you for your email. (b)(4)

(b)(4)

(b)(4) Please let me know if you have any further questions regarding this information.

Sincerely,

Stacie Gutowski, Ph.D.

Biomedical Engineer

ODE/DNPMD/NSDB

WO 66, Rm 2656

10903 New Hampshire Avenue

Silver Spring, MD 20993

(240) 402-6032

Stacie.Gutowski@fda.hhs.gov<mailto:Stacie.Gutowski@fda.hhs.gov>

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https://www.research.net/s/cdrhcustomerservice?O=400&D=460&B=462&E=&S=E

From: Kim Schmelzer [mailto:(b)(6)

Sent: Wednesday, March 02, 2016 2:51 PM

To: Gutowski, Stacie

Subject: RE: K151790/S001 Question

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

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Stacie,

I hope this email finds you well.

(b)(4)

Thank you,

Kim Schmelzer | Quality Manager

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From: Massey, Cherryace * [Cherryace.Massey@fda.hhs.gov]
Sent: 7/23/2015 6:05:26 PM
To: (b)(6)
CC: DCCLetters [DCCLetters@fda.hhs.gov]
Subject: K151790 eCopy Hold Letter w/attachment
Attachments: K151790.pdf

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

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

eCopy Hold Letter

07/23/2015

KIM SCHMELZER
QUALITY MANAGER
PMT CORPORATION
1500 PARK RD
CHANHASSEN, MN 55317
United States

Dear KIM SCHMELZER:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has received your submission. This submission has been assigned the unique document control number below. Failure to reference this assigned number in future correspondence may result in processing delays.

Submission Number: K151790
Received: 07/23/2015
Applicant: PMT CORPORATION
Device: (b)(4)

The Federal Food, Drug, and Cosmetic Act (the Act), as amended by section 1136 of the Food and Drug Administration Safety and Innovation Act (FDASIA), authorizes FDA to require an electronic copy (eCopy) for certain types of submissions. **You have received this letter because you have either not provided an eCopy or you provided an eCopy that failed the loading process because it did not meet the technical standards.** If you provided an eCopy that failed the loading process, then please see the attached document that identifies all reasons for the failure that need to be addressed. To understand the reasons for your eCopy failure, please refer to the eCopy guidance document, "eCopy Program for Medical Device Submissions" at http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM313794.pdf.

Please write the specific submission number identified above AND "Replacement eCopy" directly on the CD (or other media) and send that with a paper copy of your cover letter (revised if applicable) to the CDRH Document Control Center (DCC) at the address below.

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

When your Replacement eCopy has been received and been verified as a valid eCopy, review of this submission will start as of that date.

If you have any questions concerning this letter, please contact the eCopy Program Coordinators at (240) 402-3717 or at CDRH-eCopyinfo@fda.hhs.gov.

Sincerely yours,

Center for Devices and Radiological Health

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

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Attachment

Attachment for Submission Number(s):

K151790

The list below identifies the reason(s) why your eCopy failed FDA's eCopy validation process. All of these items need to be addressed or your eCopy will not pass the validation process.

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(b)(4)

REPORT TO: Ms. Kim Schmelzer
PMT Corporation
1500 Park Road
Chanhassen, MN 55317

TEST ARTICLE: Depthalon Depth Electrodes (b)(4)

(b)(4)

(b)(4)

(b)(4)

TEST PROCEDURE: (b)(4)

(b)(4)

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

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From: Kim Schmelzer [mailto:(b)(6)
Sent: Monday, October 19, 2015 5:04 PM
To: Gutowski, Stacie
Subject: RE: K151790/S001 Follow-up Information Request

Staci,

I hope you had a good weekend!

(b)(4)

Let me know if you have any further questions or concerns.

Thank you,
Kim Schmelzer | Quality Manager
PMT Corporation | Permark
1500 Park Road Chanhassen MN 55317 USA
D: +952.470.0866 | F: +952.470.0865
Toll Free: 1.800.MANKIND (626-5463)
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From: Gutowski, Stacie [mailto:Stacie.Gutowski@fda.hhs.gov]
Sent: Friday, October 16, 2015 7:56 AM
To: Kim Schmelzer
Cc: k151790@docs.fda.gov
Subject: RE: K151790/S001 Follow-up Information Request

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

Records processed under FOIA Request 2024-2207; Released by CDRH on 11-13-2024

Dear Ms. Schmelzer,
Thank you for following up with the requested information. (b)(4)

(b)(4)

Please let me know if you have any questions.
Stacie Gutowski, Ph.D.
Biomedical Engineer
ODE/DNPMD/NSDB
WO 66, Rm 2656
10903 New Hampshire Avenue
Silver Spring, MD 20993
(240) 402-6032
Stacie.Gutowski@fda.hhs.gov

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https://www.research.net/s/cdrhcustomerservice?O=400&D=460&B=462&E=&S=E

From: Kim Schmelzer [mailto: (b)(6)
Sent: Wednesday, October 14, 2015 2:15 PM
To: Gutowski, Stacie
Cc: k151790@docs.fda.gov
Subject: RE: K151790/S001 Follow-up Information Request

Stacie,

(b)(4)

Let me know if you have any questions or need clarification.

Thank you,
Kim Schmelzer | Quality Manager
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From: Gutowski, Stacie [mailto:Stacie.Gutowski@fda.hhs.gov]
Sent: Wednesday, October 14, 2015 11:38 AM
To: (b)(6)
Cc: k151790@docs.fda.gov
Subject: K151790/S001 Follow-up Information Request

Ms. Schmelzer,
We have completed administrative review of your submission (K151790) and have accepted the file for substantive review. (b)(4)

(b)(4) Please email me with the updated documents, and be sure to cc the docs.fda.gov email address above on all future communications for this file. You only need to send the documentation for the items requested, no need to send the whole submission again.
Please let me know if you have any questions.

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

Records processed under FOIA Request 2024-2207; Released by CDRH on 11-13-2024

Stacie Gutowski, Ph.D.
Biomedical Engineer
ODE/DNPMD/NSDB
WO 66, Rm 2656
10903 New Hampshire Avenue
Silver Spring, MD 20993
(240) 402-6032
Stacie.Gutowski@fda.hhs.gov

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https://www.research.net/s/cdrhcustomerservice?O=400&D=460&B=462&E=&S=E

From: Stacie Gutowski [mailto:stacie.gutowski@fda.hhs.gov]
Sent: Wednesday, October 14, 2015 11:50 AM
To: (b)(6)
Cc: Gutowski, Stacie
Subject: K151790/S001 was Accepted

October 14, 2015

Acceptance Review Notification - Accepted

An administrative acceptance review was conducted on your premarket notification (510(k)) K151790/S001, and it was found to contain all of the necessary elements and information needed to proceed with the substantive review. We will contact you should we require any additional information during the course of the substantive review. The lead reviewer assigned to your submission is Stacie Gutowski.

*** This is a system-generated email notification ***

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From: Smith, Alysia * [Alysia.Smith@fda.hhs.gov]
Sent: 7/1/2015 9:23:11 PM
To: (b)(6)
CC: DCCLetters [DCCLetters@fda.hhs.gov]
Subject: K151790 eCopy Hold Letter with Attachment
Attachments: K151790 eCopy Hold Letter.pdf; K151790 ATTACHMENT.pdf

Thank You,

Alysia Smith
Records Management Specialist- 510K Staff
FDA/DCC
White Oak, Silver Spring MD
Center for Devices and Radiological Health

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

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Attachment

Attachment for Submission Number(s):

K151790

The list below identifies the reason(s) why your eCopy failed FDA's eCopy validation process. All of these items need to be addressed or your eCopy will not pass the validation process.

1.

(b)(4)

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	Platinum Depthalon Biocompatibility Test Report - PMT.pdf

2. (b)(4)

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PMT® Corporation
1500 PARK ROAD · CHANHASSEN, MN 55317 USA · PHONE (952) 470-0866 · 1-800-MANKIND · FAX (952) 470-0865

(b)(4)

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Document type: TECHNICAL PROTOCOL	Document No. (b)(4)	Page 1 of 10
Document title: (b)(4)	Effective Date 4/29/11	Current Rev. (b)(4)

(b)(4)

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Document type: TECHNICAL REPORT	Document No. (b)(4)	Page 1 of 4
Document title: (b)(4)	Effective Date 6/24/2011	Current Rev. (b)(4)

(b)(4)

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Records processed under FOIA Request 2024-2207; Released by CDRH on 11-13-2024

Dear Ms. Schmelzer,
Thank you for following up with the requested information (b)(4)

(b)(4)

Please let me know if you have any questions.
Stacie Gutowski, Ph.D.
Biomedical Engineer
ODE/DNPMD/NSDB
WO 66, Rm 2656
10903 New Hampshire Avenue
Silver Spring, MD 20993
(240) 402-6032
Stacie.Gutowski@fda.hhs.gov

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From: Kim Schmelzer [mailto: (b)(6)
Sent: Wednesday, October 14, 2015 2:15 PM
To: Gutowski, Stacie
Cc: k151790@docs.fda.gov
Subject: RE: K151790/S001 Follow-up Information Request

Stacie,

(b)(4)

Let me know if you have any questions or need clarification.

Thank you,
Kim Schmelzer | Quality Manager
PMT Corporation | Permark
1500 Park Road Chanhassen MN 55317 USA
D: +952.470.0866 | F: +952.470.0865
Toll Free: 1.800.MANKIND (626-5463)
www.pmtcorp.com | www.permark.com

Description: pmt_logo

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Sent: Wednesday, October 14, 2015 11:50 AM
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Cc: Gutowski, Stacie
Subject: K151790/S001 was Accepted

October 14, 2015

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Office Location
Business Address
Phone Number

Premarket Notification [510(k)] Review

Date: July 12, 2016

Reviewer: Stacie Gutowski, Ph.D.

Subject: Traditional 510(k)# K157190

Applicant: PMT Corporation

Device Trade Name: Depthalon Depth Electrode

Contact Name: Kim Schmelzer

Contact Title: Quality Manager

Correspondent Firm:

Phone: 952-470-0866 **Email:** (b)(6)

Received Date: October 9, 2015

Due Date: December 8, 2015

Reg #: 882.1330 **Reg Name:** Depth Electrode

Class: II **Product Code(s):** GZL

Predicate Devices:

Submission #	Pro Code	Device Trade Name	Owner
K802152	GZL	PMT Depthalon Depth #2102	Progress Mankind Technology
K041604	GZL	Macro-micro Depth Electrode	Ad-tech Medical Instrument Corp.

(b)(5)

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

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Digital Signature Concurrence Table	
Reviewer Sign-Off	Stacie M. Gutowski -S 2016.07.12 09:29:53 -04'00'

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

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Document type: Validation Plan	Document No. (b)(5)	Page 1 of 8
Document title: (b)(4)	Effective Date 9/5/00	Current Rev. (b)(4)

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Traditional or Abbreviated 510(k)

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1. **Medical Device User Fee Cover Sheet**
   Please see the attached copy.

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

Records processed under FOIA Request 2024-2207; Released by CDRH on 11-13-2024
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
PMT CORP. 1500 PARK RD. P.O. BOX 610 CHANHASSEN MN 55317 US	Al Iversen 2.1 E-MAIL ADDRESS (b)(6) 2.2 TELEPHONE NUMBER (include Area code) 952-470-0866 2.3 FACSIMILE (FAX) NUMBER (Include Area code)
1.1 EMPLOYER IDENTIFICATION NUMBER (EIN) *****3591	

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.

Records processed under FOIA Request 2024-2207; Released by CDRH on 11-13-2024

[ ] 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

[ ] 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) 04-Jun-2015

FDA 3601 (05/13)

"Close Window" Print Cover sheet

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2. CDRH Premarket Review Submission Cover Sheet

Please see the attached copy.

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

Form Approval
OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on page 5.

Date of Submission	User Fee Payment ID Number	FDA Submission Document Number *(if known)*
	(b)(4)	

SECTION A TYPE OF SUBMISSION

PMA	PMA & HDE Supplement	PDP	510(k)	Request for Feedback
☐ Original Submission	☐ Regular (180 day)	☐ Original PDP	☒ Original Submission:	☐ Pre-Submission
☐ Premarket Report	☐ Special	☐ Notice of Completion	☒ Traditional	☐ Informational Meeting
☐ Modular Submission	☐ Panel Track (PMA Only)	☐ Amendment to PDP	☐ Special	☐ Submision Issue Meeting
☐ Amendment	☐ 30-day Supplement		☐ Abbreviated (Complete section I, Page 5)	☐ Day 100 Meeting
☐ Report	☐ 30-day Notice		☐ Additional Information	☐ Agreement Meeting
☐ Report Amendment	☐ 135-day Supplement		☐ Third Party	☐ Determination Meeting
☐ Licensing Agreement	☐ Real-time Review			☐ Study Risk Determination
	☐ Amendment to PMA & HDE Supplement			☐ Other *(specify)*:
	☐ Other			

IDE	Humanitarian Device Exemption (HDE)	Class II Exemption Petition	Evaluation of Automatic Class III Designation (De Novo)	Other Submission
☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ 513(g)
☐ Amendment	☐ Amendment	☐ Additional Information	☐ Additional Information	☐ Other *(describe submission)*:
☐ Supplement	☐ Supplement			
	☐ Report			
	☐ Report Amendment			

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

SECTION B SUBMITTER, APPLICANT OR SPONSOR

Company / Institution Name	Establishment Registration Number *(if known)*		
PMT Corporation	2182979		
Division Name *(if applicable)*	**Phone Number *(including area code)***		
	952-470-0866		
Street Address	**FAX Number *(including area code)***		
1500 Park Road	952-470-0866		
City	**State / Province**	**ZIP/Postal Code**	**Country**
Chanhassen	MN	55317	USA
Contact Name			
Kim Schmelzer			
Contact Title	**Contact E-mail Address**		
Quality Manager	(b)(6)		

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

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

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

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SECTION D1 REASON FOR APPLICATION - PMA, PDP, OR HDE

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

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

- ☐ Response to FDA correspondence:

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

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

- ☐ Location change:
  - ☐ Manufacturer
  - ☐ Sterilizer
  - ☐ Packager

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

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

- ☐ Other Reason *(specify)*:

SECTION D2 REASON FOR APPLICATION - IDE

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

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

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

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

- ☐ Other Reason *(specify)*:

SECTION D3 REASON FOR SUBMISSION - 510(k)

- ☐ New Device
- ☒ Additional or Expanded Indications
- ☐ Change in Technology

- ☐ Other Reason *(specify)*:

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

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SECTION E ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed

1	GZL	2		3		4	
5		6		7		8	

Summary of, or statement concerning, safety and effectiveness information

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

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

	510(k) Number	*Trade or Proprietary or Model Name*	*Manufacturer*
1	K082152	PMT Depthalon Depth Electrode Model 2102	PMT Corporation
2	K041604	Macro-Micro Electrodes	Ad-tech Corporation
3			
4			
5			
6			

SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification name

Depth Electrode, Macro Depth Electrodes, Micro Depth Electrodes, Microwire Depth Electrodes, Macro-Micro Depth Electrodes, Macro-Microwire Depth Electrodes, sEEG Depth Electrodes, Accunav Depth Electrodes

	Trade or Proprietary or Model Name for This Device	Model Number
1	(b)(4)	
2		
3		
4		
5		

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

1 K082152	2	3	4	5	6
7	8	9	10	11	12

Data Included in Submission

☒ Laboratory Testing ☐ Animal Trials ☐ Human Trials

SECTION G PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS

Product Code	C.F.R. Section *(if applicable)*	Device Class
GZL	882.1330	☐ Class I ☒ Class II ☐ Class III ☐ Unclassified

Classification Panel

Neurology

Indications *(from labeling)*

(b)(4)

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

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Note: Submission of the information entered in Section H does not affect the need to submit device establishment registration.	FDA Document Number *(if known)*

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

(b)(4)

☐ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☐ Manufacturer ☐ Contract Manufacturer ☐ Contract Sterilizer ☐ Repackager / Relabeler	
Company / Institution Name		Establishment Registration Number	
Division Name *(if applicable)*		Phone Number *(including area code)*	
Street Address		FAX Number *(including area code)*	
City		State / Province	ZIP Code / Country
Contact Name	Contact Title	Contact E-mail Address	

☐ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☐ Manufacturer ☐ Contract Manufacturer ☐ Contract Sterilizer ☐ Repackager / Relabeler	
Company / Institution Name		Establishment Registration Number	
Division Name *(if applicable)*		Phone Number *(including area code)*	
Street Address		FAX Number *(including area code)*	
City		State / Province	ZIP Code / Country
Contact Name	Contact Title	Contact E-mail Address	

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

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SECTION I — UTILIZATION OF STANDARDS

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

	Standards No.	Standards Organization	Standards Title	Version	Date
1	CFR Title 21 Part 820	FDA	Quality System Regulations	Current	
2	ISO 13485:2003	ISO	Quality System - Medical Device Particular Requirements for Application of 9001	2003	
3	BS/EN/ISO 14971:2012	ISO	Medical Devices - Application of Risk Management	2012	
4	(b)(4)				
5	IEC 60601-3 (b)(4)	IEC	Medical Electrical Equipment Part 1: General Requirements for basic Safety and Essential Performance	3rd	
6	CFR Title 21 Part 898	FDA	Performance Standard for Electrode Lead Wire and Patient Cables		
7			SEE ATTACHED SHEET FOR ADDITIONAL STANDARDS		

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

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Rockville, MD 20850

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SECTION I (continued) UTILIZATION OF STANDARDS

Additional Standards cited in this application:

ANSI/AAMI/ISO 10993-1:2003	Biological Evaluation of Medical Devices Part 1
ANSI/AAMI/ISO 10993-12:2012	Biological Evaluation of Medical Devices Part 12 – Sample preparation and reference materials.
ANSI/AAMI/ISO 10993-5:2009	Biological Evaluation of Medical Devices Part 5 – Tests for in vitro cytotoxicity
ANSI/AAMI/ISO 10993-10:2010	Biological Evaluation of Medical Devices Part 10 – Tests for irritation and delayed-type hypersensitivity
ANSI/AAMI/ISO 10993-10:2010	Biological Evaluation of Medical Devices Part 10 – Tests for irritation and delayed-type hypersensitivity
ANSI/AAMI/ISO 10993-10:2010	Biological Evaluation of Medical Devices Part 10 – Tests for irritation and delayed-type hypersensitivity
ANSI/AAMI/ISO 10993-11:2006	Biological Evaluation of Medical Devices Part 11 – Tests for Systemic Toxicity
ISO 10993-3:2003	Biological Evaluation of Medical Devices Part 3 – Tests for Genotoxicity, Carcinogenicity and Reproductive Toxicity
ISO 10993-6:2007	Biological Evaluation of Medical Devices Part 6 – Tests for Local Effects After Implantation

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Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

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

TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

(b)(4)

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☐	☒
FDA Recognition number [3] #		
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☐	☒
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☒	☐
Were there any deviations or adaptations made in the use of the standard?	☒	☐
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☒	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☒	☐
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☒

Title of guidance: _____

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

[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

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

[6] The online search for CDRH Guidance Documents can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm

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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE

(b)(4)

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
(b)(4)		
(b)(4)		
(b)(4)		
(b)(4)		

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

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

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

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PRAStaff@fda.hhs.gov

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Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

CFR Title 21 Part 898.12 - Performance Standard for Electrode Lead Wires and Patient Cables

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3] #		
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☐	☒
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☐	☒
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☒	☐
If yes, was the guidance document followed in preparation of this 510k?	☒	☐

Title of guidance: This is an FDA regulation

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

[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

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

[6] The online search for CDRH Guidance Documents can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm

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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE
CFR Title 21 Part 898.12 - Performance Standard for Electrode Lead Wires and Patient Cables

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
898.12	Performance Standard	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *
This section followed

DESCRIPTION
To comply with IEC 60601-1 (b)(4)

JUSTIFICATION
Required compliance by FDA

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

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

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

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[Code of Federal Regulations]
[Title 21, Volume 8]
[Revised as of April 1, 2014]
[CITE: 21CFR898]

TITLE 21--FOOD AND DRUGS
CHAPTER I--FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES
SUBCHAPTER H--MEDICAL DEVICES
PART 898PERFORMANCE STANDARD FOR ELECTRODE LEAD WIRES AND PATIENT CABLES

Sec. 898.11 Applicability.

Electrode lead wires and patient cables intended for use with a medical device shall be subject to the performance standard set forth in 898.12.

Sec. 898.12 Performance standard.

(a) Any connector in a cable or electrode lead wire having a conductive connection to a patient shall be constructed in such a manner as to comply with subclause 56.3(c) of the following standard:

International Electrotechnical Commission (IEC)

601-1: Medical Electrical Equipment

601-1 (1988) Part 1: General requirements for safety

Amendment No. 1 (1991)

Amendment No. 2 (1995).

(b) Compliance with the standard shall be determined by inspection and by applying the test requirements and test methods of subclause 56.3(c) of the standard set forth in paragraph (a) of this section.

Sec. 898.13 Compliance dates.

The dates for compliance with the standard set forth in 898.12(a) shall be as follows:

(a) For electrode lead wires and patient cables used with, or intended for use with, the following devices, the date for which compliance is required is May 11, 1998:

Listing of Devices for Which Compliance is Required Effective May 11, 1998

Phase	Product code	21 CFR section	Class	Device name
1	73 BZQ	868.2375	II	Monitor, Breathing Frequency.
1	73 FLS	868.2375	II	Monitor (Apnea Detector), Ventilatory Effort.
1	74 DPS	870.2340	II	Electrocardiograph.
1	74 DRG	870.2910	II	Transmitters and Receivers, Physiological Signal, Radio Frequency.

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1	74	DRT	870.2300	II	Monitor, Cardiac (including Cardiotachometer and Rate Alarm).
1	74	DRX	870.2360	II	Electrode, Electrocardiograph.
1	74	DSA	870.2900	II	Cable, Transducer and Electrode, Patient (including Connector).
1	74	DSH	870.2800	II	Recorder, Magnetic Tape, Medical.
1	74	DSI	870.1025	III	Detector and Alarm, Arrhythmia.
1	74	DXH	870.2920	II	Transmitters and Receivers, Electrocardiograph, Telephone.

(b) For electrode lead wires and patient cables used with, or intended for use with, any other device, the date for which compliance is required is May 9, 2000.

Sec. 898.14 Exemptions and variances.

(a) A request for an exemption or variance shall be submitted in the form of a petition under 10.30 of this chapter and shall comply with the requirements set out therein. The petition shall also contain the following:

(1) The name of the device, the class in which the device has been classified, and representative labeling showing the intended uses(s) of the device;

(2) The reasons why compliance with the performance standard is unnecessary or unfeasible;

(3) A complete description of alternative steps that are available, or that the petitioner has already taken, to ensure that a patient will not be inadvertently connected to hazardous voltages via an unprotected patient cable or electrode lead wire for intended use with the device; and

(4) Other information justifying the exemption or variance.

(b) An exemption or variance is not effective until the agency approves the request under 10.30(e)(2)(i) of this chapter.

Effective Date Note:

At 62 FR 25477, May 9, 1997, 898.14 was stayed pending Office of Management and Budget approval of information collection and recordkeeping requirements.

Authority: 21 U.S.C. 351, 352, 360c, 360d, 360gg-360ss, 371, 374; 42 U.S.C. 262, 264.
Source: 62 FR 25497, May 9, 1997, unless otherwise noted.

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5. http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Databases/default.htm
6. /scripts/cdrh/cfdocs/search/default.cfm?FAQ=true
7. http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Databases/ucm135680.htm

Page Last Updated: 09/01/2014

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Form Approved: OMB No. 0910-0120; Expiration Date: 1/31/2017

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

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

TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

IEC 60601-1:Edition 3.1:2012 - Medical Electrical Equipment Part 1 - General requirements for basic safety and essential performance.

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#5-89	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☐	☒
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☐	☒
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☐
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☒

Title of guidance: _____

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

[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

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

[6] The online search for CDRH Guidance Documents can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm

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

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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
IEC 60601-1:Edition 3.1:2012 - Medical Electrical Equipment Part 1 - General requirements for basic safety and essential performance.

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
(b)(4)	(b)(4)	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *
This section followed

DESCRIPTION
(b)(4)

JUSTIFICATION
Required for compliance with Title 21 CFR 898-12

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
(b)(4)	Multiple sections	☐ Yes ☐ No ☒ N/A

TYPE OF DEVIATION OR OPTION SELECTED *
(b)(4)

(b)(4)

(b)(4)

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

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

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

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

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

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Recognized Consensus Standards

Recognition List Number: 036 **FR Publication Date:** 07/09/2014

Part B: Supplementary Information

Recognition Number 5-89: IEC 60601-1-6 Edition 3.1 2013-10, Medical Electrical Equipment ¿ Part 1-6: General Requirements For Basic Safety And Essential Performance ¿ Collateral Standard: Usability. (General I (QS/RM))

Date of Standard: 2013.

Address of Standards Development Organization:

International Electrotechnical Commission (IEC)
3, Rue de Varembe'
PO Box 131
CH-1211 Geneva 20, 0

SWITZERLAND

CDRH Office and Division associated with recognized standards:

ALL OFFICES AND DIVISIONS IN CDRH

Devices Affected:

All medical devices

Processes Affected:

510(k), PMA, IDE, PMA, PDP, HDE

Type of Standard:

Horizontal, International

Extent of Recognition:

Complete standard

Transition:

FDA recognition of IEC 60601-1-6 Edition 3.0 2010-01 [Rec#5-85] will be superseded by recognition of IEC 60601-1-6 Edition 3.1 2013-10 [Rec#5-89]. FDA will accept declarations of conformity, in support of premarket submissions, to [Rec#5-85] until August 1, 2016. After this transition period, declarations of conformity to [Rec#5-85] will not be accepted.

Records processed under FOIA Request 2024-2207; Released by CDRH on 11-13-2024

Relevant Guidance:

CDRH Publication: "Medical Device Use-Safety: Incorporating Human Factors Into Risk Management,: Document Issued On July 18, 2000

CDRH Publication (Draft): "Applying Human Factors And Usability Engineering To Optimize Medical Device Design," Document Issued On June 22, 2011

AAMI TIR50:2014 Post-Market Surveillance Of Use Error Management

FDA Technical Contact:

Ron D. Kaye
FDA/CDRH/ODE
10903 New Hampshire Avenue Building 66, Room 2520
Silver Spring MD 20993
301/796-6289
email: ron.kaye@fda.hhs.gov

*** in the United States, copies of this standard can be obtained from:**
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25 West 43rd Street
4th Floor
New York, NY 10036

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10903 New Hampshire Avenue
Silver Spring, MD 20993
Ph. 1-888-INFO-FDA (1-888-463-6332)
Contact FDA

USA.gov

For Government For Press

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U.S. Department of **Health & Human Services**

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Form Approved: OMB No. 0910-0120; Expiration Date: 1/31/2017

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

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

TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ANSI/AAMI/ISO 10993-1:2009 - Biological Evaluation of Medical Devices Part 1

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#2-156	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☒	☐
If yes, was the guidance document followed in preparation of this 510k?	☒	☐

Title of guidance: FDA Bluebook Memorandum G95-1

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

[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

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

[6] The online search for CDRH Guidance Documents can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm

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

Records processed under FOIA Request 2024-2207; Released by CDRH on 11-13-2024

Recognition List Number: 036 **FR Publication Date:** 07/09/2014

Part B: Supplementary Information

Recognition Number 2-156: AAMI / ANSI / ISO 10993-1:2009/(R) 2013, Biological Evaluation Of Medical Devices -- Part 1: Evaluation And Testing Within A Risk Management Process. (Biocompatibility)

Date of Standard: 2009.

Addresses of Standards Development Organizations:

Association for the Advancement of Medical Instrumentation (AAMI)
4301 North Fairfax Drive
Suite 301
Arlington, VA 22203

American National Standards Institute (ANSI)
25 West 43rd Street
4th Floor
New York, NY 10036

International Organization for Standardization (ISO)*
1, Rue de Varembe
Case Postale 56
CH 1211 Geneva 20, 0

SWITZERLAND

CDRH Office and Division associated with recognized standards:

OFFICE OF DEVICE EVALUATION (*ODE*)

Devices Affected:

All devices that contact body tissues

Processes Affected:

510(k), PMA, IDE, PDP, HDE, Design Control Input, Quality System Regulation

Type of Standard:

International, Horizontal

Extent of Recognition:

Complete standard with the following exception:

Records processed under FOIA Request 2024-2207; Released by CDRH on 11-13-2024

Section 4 General principles

Section 5.2.3 Implant devices

Section 6.1 Material characterization

The last sentence of paragraph 6 is excluded.

Section 6.2 Biological evaluation tests

Clause 6.2.1 (General)

Clause 6.2.2.7 (Test descriptions - Genotoxcity): Exclude second paragraph

Clause 6.2.2.11 (Test descriptions - Carcinogenicity): Exclude second sentence

Clause 6.2.2.12 Exclude third and fourth sentences

Clause 6.2.2.13 Exclude the paragraph that states "Biodegradation tests might not be necessary if the probable products of degradation are in the predicted quantities, and produced at a rate similar to those that have a history of safe clinical use; and/or if particulate, they are present in a physical state, i.e., size distribution and shape, similar to those with a history of safe clinical use; or sufficient degradation data relevant to the substances and degradation products in the intended use already exists."

Annex A Biological evaluation tests

Exclude Annex A. Instead, use G95-1 which identifies the CDRH recommended tests based on type and duration of contact (see CDRH guidance citation below).

Prior to conducting studies for in situ polymerizing materials, or submicron components, contact the reviewing division.

Related CFR Citations and Product Codes:

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

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Regulation Number	Device Name	Device Class	Product Code

Relevant Guidance:

Appendix I Of FDA's "Draft Guidance For Preparation Of PMA Applications For Testicular Prostheses" For Extraction Guidance For Polymeric Implants.

ISO 10993-12:2012: Biological Evaluation Of Medical Devices -- Part 12: Sample Preparation And Reference Materials

FDA Bluebook Memorandum G95-1 "Use Of International Standard ISO 10993, 'Biological Evaluation Of Medical Devices Part 1: Evaluation And Testing'."

FDA Draft Guidance "Use Of International Standard ISO-10993, Biological Evaluation Of Medical Devices Part 1: Evaluation And Testing" Which, When Final, Will Represent The Agency's Thinking On This Topic.

FDA Technical Contacts:

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Silver Spring MD 20993
301/796-6530
email: michael.bailey@fda.hhs.gov

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

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Form Approved: OMB No. 0910-0120; Expiration Date: 1/31/2017

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

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

TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ANSI/AAMI/ISO 10993-12:2012 - Biological Evaluation of Medical Devices Part 12 - Sample Preparation and Reference Materials

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3] #2-198		
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☒	☐
If yes, was the guidance document followed in preparation of this 510k?	☒	☐

Title of guidance: FDA Bluebook Memorandum G95-1

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

[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

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

[6] The online search for CDRH Guidance Documents can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm

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

Records processed under FOIA Request 2024-2207; Released by CDRH on 11-13-2024

Recognition List Number: 031 **FR Publication Date:** 08/05/2013

Part B: Supplementary Information

Recognition Number 2-198: AAMI / ANSI / ISO 10993-12:2012, Biological Evaluation Of Medical Devices -- Part 12: Sample Preparation And Reference Materials. (Biocompatibility)

Date of Standard: 2012.

Addresses of Standards Development Organizations:

Association for the Advancement of Medical Instrumentation (AAMI)
4301 North Fairfax Drive
Suite 301
Arlington, VA 22203

American National Standards Institute (ANSI)
25 West 43rd Street
4th Floor
New York, NY 10036

International Organization for Standardization (ISO)*
1, Rue de Varembe
Case Postale 56
CH 1211 Geneva 20, 0

SWITZERLAND

CDRH Office and Division associated with recognized standards:

OFFICE OF DEVICE EVALUATION (*ODE*)

Devices Affected:

All medical devices where biological evaluation and physico-chemical characterization is needed

Processes Affected:

510(k), PMA, IDE, PDP, HDE, Design Control Input, Quality System Regulation

Type of Standard:

International, Horizontal

Extent of Recognition:

Complete standard with any annexes with the following exceptions:

Records processed under FOIA Request 2024-2207; Released by CDRH on 11-13-2024

Clause 2.0 "Normative references": those references which CDRH does not currently recognize - are excluded from this recognition (per "Frequently Asked Questions on Recognition of Consensus Standards; Guidance for Industry and for FDA Staff," dated July 22, 2002.)

Clause 10.3.1 a): extraction condition of (37 ± 1) °C for (72 ± 2) h for prolonged contact devices and permanent implants - is not recognized. Prior to conducting studies using this extraction condition for prolonged contact devices and permanent implants, contact the reviewing division.

Clause 10.3.10: exhaustive extraction "For hazard identification of polymeric devices" (per Annex D) ¿ is not recognized. Prior to conducting studies using exhaustive extraction conditions, contact the reviewing division.

Exclude Clause 10.4.3.

Prior to conducting studies for in situ polymerizing materials, or submicron components, contact the reviewing division.

Related CFR Citations and Product Codes:

Regulation Number	Device Name	Device Class	Product Code

Relevant Guidance:

FDA Bluebook Memorandum G95-1 "Use Of International Standard ISO-10993, 'Biological Evaluation Of Medical Devices Part 1: Evaluation And Testing'."

FDA Draft Guidance ¿Use Of International Standard ISO-10993, Biological Evaluation Of Medical Devices Part 1: Evaluation And Testing" Which, When Final, Will Represent The Agency¿S Thinking On This Topic.

FDA Technical Contact:

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Form Approved: OMB No. 0910-0120; Expiration Date: 1/31/2017

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

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

TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ANSI/AAMI/ISO 10993-5:2009 - Biological Evaluation of Medical Devices Part 5 - Test for In vitro Cytotoxicity

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#2-153	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☒	☐
If yes, was the guidance document followed in preparation of this 510k?	☒	☐

Title of guidance: FDA Bluebook Memorandum G95-1

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

[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

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

[6] The online search for CDRH Guidance Documents can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm

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

Recognized Consensus Standards

Recognition List Number: 036 **FR Publication Date:** 07/09/2014

Part B: Supplementary Information

Recognition Number 2-153: AAMI / ANSI / ISO 10993-5:2009/(R) 2014, Biological Evaluation Of Medical Devices -- Part 5: Tests For In Vitro Cytotoxicity. (Biocompatibility)

Date of Standard: 2009.

Addresses of Standards Development Organizations:

Association for the Advancement of Medical Instrumentation (AAMI)
4301 North Fairfax Drive
Suite 301
Arlington, VA 22203

American National Standards Institute (ANSI)
25 West 43rd Street
4th Floor
New York, NY 10036

International Organization for Standardization (ISO)*
1, Rue de Varembe
Case Postale 56
CH 1211 Geneva 20, 0

SWITZERLAND

CDRH Office and Division associated with recognized standards:

OFFICE OF DEVICE EVALUATION (*ODE*)

Devices Affected:

All medical devices contacting patients directly or indirectly

Processes Affected:

510(K), PMA, IDE, PDP, HDE

Type of Standard:

International, Horizontal

Extent of Recognition:

Complete standard

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Prior to conducting studies for in situ polymerizing materials, or submicron components, contact the reviewing division.

Related CFR Citations and Product Codes:

Regulation Number	Device Name	Device Class	Product Code

Relevant Guidance:

ISO 10993-12:2012: Biological Evaluation Of Medical Devices -- Part 12: Sample Preparation And Reference Materials

FDA Bluebook Memorandum G95-1 "Use Of International Standard ISO 10993, 'Biological Evaluation Of Medical Devices Part 1: Evaluation And Testing.'

FDA's "Draft Guidance For Preparation Of PMA Applications For Testicular Prostheses"

FDA Draft Guidance "Use Of International Standard ISO-10993, Biological Evaluation Of Medical Devices Part 1: Evaluation And Testing" Which, When Final, Will Represent The Agency's Thinking On This Topic.

FDA Technical Contacts:

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301/796-0258
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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Form Approved: OMB No. 0910-0120; Expiration Date: 1/31/2017

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

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

TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ANSI/AAMI/ISO 10993-10:2010 - Biological Evaluation of Medical Devices Part 10 - Tests for Irritation and Delayed-type Hypersensitivity

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#2-173	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☒	☐
If yes, was the guidance document followed in preparation of this 510k?	☒	☐

Title of guidance: FDA Bluebook Memorandum G95-1

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

[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

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

[6] The online search for CDRH Guidance Documents can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm

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

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Recognized Consensus Standards

Recognition List Number: 034 **FR Publication Date:** 01/30/2014

Part B: Supplementary Information

Recognition Number 2-173: AAMI / ANSI / ISO 10993-10:2010, Biological Evaluation Of Medical Devices - Part 10: Tests For Irritation And Skin Sensitization. (Biocompatibility)

Date of Standard: 2010.

Addresses of Standards Development Organizations:

Association for the Advancement of Medical Instrumentation (AAMI)
4301 North Fairfax Drive
Suite 301
Arlington, VA 22203

American National Standards Institute (ANSI)
25 West 43rd Street
4th Floor
New York, NY 10036

International Organization for Standardization (ISO)*
1, Rue de Varembe
Case Postale 56
CH 1211 Geneva 20, 0

SWITZERLAND

CDRH Office and Division associated with recognized standards:

OFFICE OF DEVICE EVALUATION (*ODE*)

Devices Affected:

All medical devices

Processes Affected:

510(k), PMA, IDE, PDP, HDE, Design Control Input, Quality System Regulation

Type of Standard:

Horizontal, International

Extent of Recognition:

Complete standard with the following exceptions

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NOTE 2: Exclude this note

Annex B.4: Penile irritation test; contact the review division prior to initiating any studies

Annex B.5: Rectal irritation test; contact the review division prior to initiating any studies

Annex B.6: Vaginal irritation test; contact the review division prior to initiating any studies

Prior to conducting studies for in situ polymerizing materials, or submicron components, contact the reviewing division.

Related CFR Citations and Product Codes:

Regulation Number	Device Name	Device Class	Product Code

Relevant Guidance:

ISO 10993-12:2012 Biological Evaluation Of Medical Devices - Part 12: Sample Preparation And Reference Materials

For Further Guidance, See FDA Bluebook Memorandum G95-1 "Use Of International Standard ISO-10993, 'Biological Evaluation Of Medical Devices Part 1: Evaluation And Testing'."

See Appendix 1 Of FDA's "Draft Guidance For Preparation Of PMA Applications For Testicular Prostheses" For Extraction Guidance For Polymeric Implants

For Further Information On Use Of The LLNA Method See FDA¿S January 13, 2011 Letter To RADM Stokes, National Toxicology Program Regarding FDA Use Of The ICCVAM Methods For LLNA.

FDA Draft Guidance "Use Of International Standard ISO-10993, Biological Evaluation Of Medical Devices Part 1: Evaluation And Testing" Which, When Final, Will Represent The Agency's Thinking On This Topic.

FDA Technical Contacts:

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

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U.S. Department of **Health & Human Services**

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Records processed under FOIA Request 2024-2207; Released by CDRH on 11-13-2024

Form Approved: OMB No. 0910-0120; Expiration Date: 1/31/2017

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

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

TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ANSI/AAMI/ISO 10993-11:2006 - Biological Evaluation of Medical Devices Part 11 - Tests for Systemic Toxicity

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#2-118	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☒	☐
If yes, was the guidance document followed in preparation of this 510k?	☒	☐

Title of guidance: FDA Bluebook Memorandum G95-1

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

[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

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

Recognized Consensus Standards

Recognition List Number: 034 **FR Publication Date:** 01/30/2014

Part B: Supplementary Information

Recognition Number 2-118: AAMI / ANSI / ISO 10993-11:2006/(R)2010, Biological Evaluation Of Medical Devices -- Part 11: Tests For Systemic Toxicity. (Biocompatibility)

Date of Standard: 2006.

Addresses of Standards Development Organizations:

Association for the Advancement of Medical Instrumentation (AAMI)
4301 North Fairfax Drive
Suite 301
Arlington, VA 22203

American National Standards Institute (ANSI)
25 West 43rd Street
4th Floor
New York, NY 10036

International Organization for Standardization (ISO)*
1, Rue de Varembe
Case Postale 56
CH 1211 Geneva 20, 0

SWITZERLAND

CDRH Office and Division associated with recognized standards:

OFFICE OF DEVICE EVALUATION (*ODE*)

Devices Affected:

Surface devices contacting mucosal membranes and breached or compromised surfaces

All external communicating devices

All implant devices

Processes Affected:

510(k), PMA, IDE, PDP, HDE, Design Control Input, Quality System Regulation

Type of Standard:

Records processed under FOIA Request 2024-2207; Released by CDRH on 11-13-2024

International, Horizontal

Extent of Recognition:

Complete standard, except Annex F.

Prior to conducting studies for in situ polymerizing materials, or submicron components, contact the reviewing division.

Related CFR Citations and Product Codes:

Regulation Number	Device Name	Device Class	Product Code

Relevant Guidance:

ISO 10993-12:2007: Biological Evaluation Of Medical Devices -- Part 12: Sample Preparation And Reference Materials

FDA Bluebook Memorandum G95-1 "Use Of International Standard ISO 10993, 'Biological Evaluation Of Medical Devices Part 1: Evaluation And Testing'."

Appendix 1 Of FDA's "Draft Guidance For Preparation Of PMA Applications For Testicular Prostheses" For Extraction Guidance For Polymeric Implants

FDA Technical Contacts:

Ronald Brown
FDA/CDRH/OSEL
10903 New Hampshire Avenue Building 64, Room 4062
Silver Spring MD 20993
301/796-0252
email: ronald.brown@fda.hhs.gov

Rakhi Dalal, Ph.D.
FDA/CDRH/OC
10903 New Hampshire Avenue Building 66, Room 3646
Silver Spring MD 20993
301/796-6418
email: rakhi.dalal@fda.hhs.gov

*** in the United States, copies of this standard can be obtained from:**
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25 West 43rd Street
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5. http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Databases/default.htm
6. /scripts/cdrh/devicesatfda/index.cfm
7. /scripts/cdrh/cfdocs/cfPMN/pmn.cfm
8. /scripts/cdrh/cfdocs/cfpmn/denovo.cfm

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5. http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Databases/default.htm
6. /scripts/cdrh/devicesatfda/index.cfm
7. /scripts/cdrh/cfdocs/cfPMN/pmn.cfm
8. /scripts/cdrh/cfdocs/cfpmn/denovo.cfm

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

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9. /scripts/cdrh/cfdocs/cfRL/rl.cfm
10. /scripts/cdrh/cfdocs/cfMAUDE/TextSearch.cfm
11. /scripts/cdrh/cfdocs/cfRES/res.cfm
12. /scripts/cdrh/cfdocs/cfPMA/pma.cfm
13. /scripts/cdrh/cfdocs/cfHDE/hde.cfm
14. /scripts/cdrh/cfdocs/cfPCD/classification.cfm
15. /scripts/cdrh/cfdocs/cfStandards/search.cfm
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17. /scripts/cdrh/cfdocs/cfPCD_RH/classification.cfm
18. /scripts/cdrh/cfdocs/cfAssem/assembler.cfm
19. /scripts/cdrh/cfdocs/Medsun/searchReportText.cfm
20. /scripts/cdrh/cfdocs/cfClia/Search.cfm
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Form Approved: OMB No. 0910-0120; Expiration Date: 1/31/2017

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

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

TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ANSI/AAMI/ISO 10993-3:2003 - Biological Evaluation of Medical Devices Part 3 - Tests for Genotoxicity, Carcinogenicity and Reproductive Toxicity

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#2-175	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☒	☐
If yes, was the guidance document followed in preparation of this 510k?	☒	☐

Title of guidance: FDA Bluebook Memorandum G95-1

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

[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

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

[6] The online search for CDRH Guidance Documents can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm

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Recognition List Number: 036 **FR Publication Date:** 07/09/2014

Part B: Supplementary Information

Recognition Number 2-175: ISO 10993-3 Second Edition 2003-10-15, Biological Evaluation Of Medical Devices Part 3: Tests For Genotoxicity, Carcinogenicity And Reproductive Toxicity. (Biocompatibility)

Date of Standard: 2003.

Address of Standards Development Organization:

International Organization for Standardization (ISO)*
1, Rue de Varembe
Case Postale 56
CH 1211 Geneva 20, 0

SWITZERLAND

CDRH Office and Division associated with recognized standards:

OFFICE OF DEVICE EVALUATION (*ODE*)

Devices Affected:

All permanent surface devices that contact mucosal membrane and breached or compromised surfaces. Permanent external communicating devices that contact blood path indirectly

Prolonged and permanent external communicating devices that contact tissue/bone/dentin

All external communicating devices that contact the circulating blood. All prolonged and permanent contact implant devices

Processes Affected:

510(k), PMA, IDE, PDP, HDE

Type of Standard:

Horizontal, International

Extent of Recognition:

Complete standard with the following exceptions:

Clause 2.0 "Normative references": those references which CDRH does not currently recognize - are excluded from this recognition (see "Frequently Asked

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Questions on Recognition of Consensus Standards; Guidance for Industry and for FDA Staff," dated July 22, 2002.)

Clause 4.1 Exclude the second, third and fourth sentences of the second paragraph as follows:

Testing for genotoxicity, however, is not necessary for medical devices, and components thereof, made only from materials known to show no genotoxicity. Testing for genotoxicity is indicated where a review of the composition of the materials reveals the possible presence in the final medical device of compounds that might interact with genetic material, or when the chemical composition of the medical device is unknown. In such circumstances, the genotoxic potential of suspect chemical components should be assessed, bearing in mind the potential for synergy, in preference to carrying out genotoxicity tests on the material or medical device as a whole. ¿ Also exclude the third paragraph.

Clause 4.2.2

Clause 4.2.4 Exclude item c.

Clause 4.3.1 ¿ Exclude the third sentence.

Clause 5.0 Contact the reviewing division prior to testing according to this section.

Clause 5.1 Exclude the note.

Clause 5.2.1, item a, exclude the qualifying phrase ¿unless there are significant and adequate data on human use or exposure¿

Clause 5.2.1, item b

Prior to conducting studies for in situ polymerizing materials, or submicron components, contact the reviewing division.

Relevant Guidance:

FDA Draft Guidance ¿Use Of International Standard ISO-10993, Biological Evaluation Of Medical Devices Part 1: Evaluation And Testing¿ Which, When Final, Will Represent The Agency¿S Thinking On This Topic.

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FDA Technical Contacts:

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Silver Spring MD 20993
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11. /scripts/cdrh/cfdocs/cfRES/res.cfm
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7. /scripts/cdrh/cfdocs/cfPMN/pmn.cfm
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9. /scripts/cdrh/cfdocs/cfRL/rl.cfm
10. /scripts/cdrh/cfdocs/cfMAUDE/TextSearch.cfm
11. /scripts/cdrh/cfdocs/cfRES/res.cfm
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14. /scripts/cdrh/cfdocs/cfPCD/classification.cfm
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16. /scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm
17. /scripts/cdrh/cfdocs/cfPCD_RH/classification.cfm
18. /scripts/cdrh/cfdocs/cfAssem/assembler.cfm
19. /scripts/cdrh/cfdocs/Medsun/searchReportText.cfm
20. /scripts/cdrh/cfdocs/cfClia/Search.cfm
21. /scripts/cdrh/cfdocs/cfTPLC/tplc.cfm
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Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ANSI/AAMI/ISO 10993-6:2007 - Biological Evaluation of Medical Devices Part 6 - Tests for Local Effects After Implantation

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#2-120	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☒	☐
If yes, was the guidance document followed in preparation of this 510k?	☒	☐

Title of guidance: FDA Bluebook Memorandum G95-1

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

[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

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

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

Recognized Consensus Standards

Recognition List Number: 034 **FR Publication Date:** 01/30/2014

Part B: Supplementary Information

Recognition Number 2-120: AAMI / ANSI / ISO 10993-6:2007/(R)2010, Biological Evaluation Of Medical Devices -- Part 6: Tests For Local Effects After Implantation. (Biocompatibility)

Date of Standard: 2007.

Addresses of Standards Development Organizations:

Association for the Advancement of Medical Instrumentation (AAMI)
4301 North Fairfax Drive
Suite 301
Arlington, VA 22203

American National Standards Institute (ANSI)
25 West 43rd Street
4th Floor
New York, NY 10036

International Organization for Standardization (ISO)*
1, Rue de Varembe
Case Postale 56
CH 1211 Geneva 20, 0

SWITZERLAND

CDRH Office and Division associated with recognized standards:

OFFICE OF DEVICE EVALUATION (*ODE*)

Devices Affected:

All medical devices contacting patients directly or indirectly

Processes Affected:

510(k), PMA, IDE, PDP, HDE

Type of Standard:

International, Horizontal

Extent of Recognition:

Complete standard with the following exceptions; (Annex A, Annex E and the Bibliography.)

Prior to conducting studies for in situ polymerizing materials, or submicron components, contact the reviewing division.

Related CFR Citations and Product Codes:

Regulation Number	Device Name	Device Class	Product Code

Relevant Guidance:

FDA Draft Guidance "Use Of International Standard ISO-10993, Biological Evaluation Of Medical Devices Part 1: Evaluation And Testing" Which, When Final, Will Represent The Agency's Thinking On This Topic.

FDA Technical Contacts:

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7. /scripts/cdrh/cfdocs/cfPMN/pmn.cfm
8. /scripts/cdrh/cfdocs/cfpmn/denovo.cfm
9. /scripts/cdrh/cfdocs/cfRL/rl.cfm
10. /scripts/cdrh/cfdocs/cfMAUDE/TextSearch.cfm
11. /scripts/cdrh/cfdocs/cfRES/res.cfm
12. /scripts/cdrh/cfdocs/cfPMA/pma.cfm
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PMT®

1500 Park Road • Chanhassen, MN 55317 USA • Phone (952) 470-0866 • Fax (952) 470-0865 • www.pmtcorp.com

3. 510(K) Cover Letter

Please see the attached cover letter.

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

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September 30, 2015

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

Reference: K151790 – PMT® Platinum Depthalon® Depth Electrode (b)(4)

To Whom It May Concern:

Per your email received 7/31/2015. PMT hereby submits this replacement paper copy and eCopy for the Platinum Depthalon Depth Electrode product family 510(k) submittal K151790.

There have been no previous submissions for the subject device.

This submission contains confidential commercial and trade secret information. We respectfully request that you give this notification the maximum protection provided by law.

Thank you in advance for your consideration of this application. If there are any questions, please contact me at 952-470-0866 or (b)(6)

Sincerely,

(b)(6)

Kim Schmelzer
Quality Manager
PMT Corporation

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

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4. Indications for Use Statement

Please see the attached Indications for Use Statement

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

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Indications for Use Statement

510(k) Number (if known): K151790

Device Name

PMT® Platinum Depthalon® Depth Electrodes

Indications for Use

The Platinum Depthalon® Depth Electrodes are intended for temporary (<30 day) use with recording, monitoring, and stimulation equipment for the recording, monitoring and stimulation of electrical signals in the subsurface of the brain.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use __X___ OR Over the Counter Use_____
(Per 21 CFR 801.109

(Optimal Format 1-2-96)

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

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5. 510(k) Statement

Please see the attached 510(k) Statement

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

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PMT Corporation
510(k) Statement

510(k) Number: K151790

I certify that, in my capacity as Quality Manager of PMT Corporation, I will make available all information included in this premarket notification on safety and effectiveness within 30 days of request by any person if the device described in the premarket notification submission is determined to be substantially equivalent. The information I agree to make available will be a duplicate of the premarket notification submission, including any adverse safety and effectiveness information, but excluding all patient identifiers, and trade secret and confidential commercial information, as defined in 21 CFR 20.61.

(b)(6)

Date: 9/30/15

Kim Schmelzer (b)(6)
Quality Manager
PMT Corporation

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

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6. Truthful and Accuracy Statement

Please see the following page for the Truthful and Accurate Statement

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

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Truthful and Accurate Statement

[As required by 21 CFR 807.87(j)]

I certify that, in my capacity as Quality Manager of PMT, I believe to the best of my knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.

(b)(6)

Kim Schmelzer (b)(6)

9/30/15

Date

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

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7. Class III Summary and Certification

This Section Does Not Apply.

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

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8. Financial Certification or Disclosure Statement

This Section Does Not Apply.

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

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9. Summary Reports

Performance Characteristics:

No Food and Drug and Cosmetic Act performance standards currently exist for Depth Electrodes.

Biocompatibility

Biological evaluation test was conducted (b)(4) (b)(4) The following tests were conducted. All items tested passed the tests conducted. The reports contain a list of the items tested during biocompatibility testing. The test protocol and reports are located in Exhibit B.

The following table is a list of tests performed and the outcome.

Test	Standard	Description	Test Outcome
(b)(4)	ANSI/AAMI/ISO 10993-1:2003	Biological Evaluation of Medical Devices Part 1	Passed
	ANSI/AAMI/ISO 10993-12:2012	Biological Evaluation of Medical Devices Part 12 – Sample preparation and reference materials.	Passed
	ANSI/AAMI/ISO 10993-5:2009	Biological Evaluation of Medical Devices Part 5 – Tests for in vitro cytotoxicity	Passed
	ANSI/AAMI/ISO 10993-10:2010	Biological Evaluation of Medical Devices Part 10 – Tests for irritation and delayed-type hypersensitivity	Passed
	ANSI/AAMI/ISO 10993-10:2010	Biological Evaluation of Medical Devices Part 10 – Tests for irritation and delayed-type hypersensitivity	Passed
	ANSI/AAMI/ISO 10993-10:2010	Biological Evaluation of Medical Devices Part 10 – Tests for irritation and delayed-type hypersensitivity	Passed
	ANSI/AAMI/ISO 10993-11:2006	Biological Evaluation of Medical Devices Part 11 – Tests for Systemic Toxicity	Passed
	ISO 10993-3:2003	Biological Evaluation of Medical Devices Part 3 – Tests for Genotoxicity, Carcinogenicity and Reproductive Toxicity	Passed
	ISO 10993-3:2003	Biological Evaluation of Medical Devices Part 3 – Tests for Genotoxicity, Carcinogenicity and Reproductive Toxicity	Passed
	ISO 10993-3:2003	Biological Evaluation of Medical Devices Part 3 – Tests for Genotoxicity, Carcinogenicity and Reproductive Toxicity	Passed
	ISO 10993-6:2007	Biological Evaluation of Medical Devices Part 6 – Tests for Local Effects After Implantation	Passed

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

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9. Summary Reports Continued

Biocompatibility

Materials for the devices are as follows:

(b)(4)

Biocompatibility testing was conducted (b)(4)

(b)(4)

Below is a list of the model # and quantity of each model used in biocompatibility testing:

(b)(4)

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

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9. Summary Reports Continued

(b)(4)

I hereby declare that the device will not be marketed until it meets the requirements of each of the standards set forth in this submission.

(b)(6)

Kim Schmelzer, Quality Manager, PMT

9/30/15

Date

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

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10. Executive Summary

(b)(4)

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

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(b)(4)

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

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11. Device Description

(b)(4)

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

Records processed under FOIA Request 2024-2207; Released by CDRH on 11-13-2024

(b)(4)

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

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12. Substantial Equivalence Discussion

The PMT Platinum Depthalon® Depth Electrodes are substantially equivalent to the current PMT Depthalon® Depth Electrode (K802152) and the Ad-tech Corporation Macro-Micro Electrodes (K041604) based on the following information.

(b)(4)

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

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Substantial Equivalence Discussion Continued

(b)(4)

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

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13. Proposed Labeling

(b)(4)

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

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14. Sterilization and Shelf Life

i. Sterilization:

The Platinum Depthalon® product family is sterilized using Ethylene Oxide (EtO) and adhere's to ISO 11135-1:2007 and EN 556-1:2001. The ETO sterilization method has been validated to a SAL of 10^{-6}.

(b)(4)

See Exhibit A for product packaging description.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8148

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Sterilization and Shelf Life Continued

Shelf Life:

(b)(4)

(b)(4) See Exhibit F for protocol and test reports.

Tyvek Pouch Package Testing

(b)(4)

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

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Sterilization and Shelf Life Continued

(b)(4)

Based on ISO 11607-1:2006, testing that a sterile barrier system maintains integrity over time will confirm sterility such that separate sterility testing is not necessary. Therefore, product packaging (Tyvek pouches and trays with Tyvek lids) has been tested by dye penetration. All packages passed the dye penetration testing.

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

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15. Biocompatibility

Biological evaluation test was conducted at (b)(4) (b)(4) The following tests were conducted. All items tested passed the tests conducted. The reports contain a list of the items tested during biocompatibility testing. The test protocol and reports are located in Exhibit B.

Test	Standard	Description	Test Outcome
(b)(4)	ANSI/AAMI/ISO 10993-1:2003	Biological Evaluation of Medical Devices Part 1	Passed
	ANSI/AAMI/ISO 10993-12:2012	Biological Evaluation of Medical Devices Part 12 – Sample preparation and reference materials.	Passed
	ANSI/AAMI/ISO 10993-5:2009	Biological Evaluation of Medical Devices Part 5 – Tests for in vitro cytotoxicity	Passed
	ANSI/AAMI/ISO 10993-10:2010	Biological Evaluation of Medical Devices Part 10 – Tests for irritation and delayed-type hypersensitivity	Passed
	ANSI/AAMI/ISO 10993-10:2010	Biological Evaluation of Medical Devices Part 10 – Tests for irritation and delayed-type hypersensitivity	Passed
	ANSI/AAMI/ISO 10993-10:2010	Biological Evaluation of Medical Devices Part 10 – Tests for irritation and delayed-type hypersensitivity	Passed
	ANSI/AAMI/ISO 10993-11:2006	Biological Evaluation of Medical Devices Part 11 – Tests for Systemic Toxicity	Passed
	ISO 10993-3:2003	Biological Evaluation of Medical Devices Part 3 – Tests for Genotoxicity, Carcinogenicity and Reproductive Toxicity	Passed
	ISO 10993-3:2003	Biological Evaluation of Medical Devices Part 3 – Tests for Genotoxicity, Carcinogenicity and Reproductive Toxicity	Passed
	ISO 10993-3:2003	Biological Evaluation of Medical Devices Part 3 – Tests for Genotoxicity, Carcinogenicity and Reproductive Toxicity	Passed
	ISO 10993-6:2007	Biological Evaluation of Medical Devices Part 6 – Tests for Local Effects After Implantation	Passed

Please see Exhibit B for testing (b)(4)

Materials for the devices are as follows:

(b)(4)

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

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16. Software

This Section Does Not Apply.

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

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17. Electromagnetic Compatibility and Electrical Safety

This Section Does Not Apply

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

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18. Performance Testing

No Food and Drug and Cosmetic Act performance standards currently exist for the Platinum Depthalon® Depth Electrodes.

Please see Exhibit D for performance testing conducted by PMT corporation.

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

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19. Performance Animal

This Section Does Not Apply

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

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20. Performance Clinical

This Section Does Not Apply

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21. Others

This Section Does Not Apply

Hello Kim,
Please see the interactive deficiencies below regarding your (b)(4) Please keep in mind that we are actively reviewing your file and we may contact you for additional information in the coming days. As before, please respond to these deficiencies direct to me via email, and be sure to cc the document email box (K151790@docs.fda.gov). Please respond by 8am (eastern time) on Wednesday June 29, 2016. Let me know if you have any questions.

(b)(4)

Sincerely,
Stacie Gutowski, Ph.D.
Biomedical Engineer
ODE/DNPMD/NSDB
WO 66, Rm 2656
10903 New Hampshire Avenue
Silver Spring, MD 20993
(240) 402-6032
Stacie.Gutowski@fda.hhs.gov

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https://www.research.net/s/cdrhcustomerservice?O=400&D=460&B=462&E=&S=E

From: Kim Schmelzer [mailto:(b)(6)
Sent: Thursday, June 23, 2016 11:00 AM
To: Gutowski, Stacie
Subject: RE: Please Confirm

Stacie,

(b)(4)

Thank you,
Kim Schmelzer | Quality Manager
PMT Corporation | Permark
1500 Park Road Chanhassen MN 55317 USA
D: +952.470.0866 | F: +952.470.0865
www.pmtcorp.com | www.permark.com

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From: Gutowski, Stacie [mailto:Stacie.Gutowski@fda.hhs.gov]
Sent: Thursday, June 23, 2016 8:36 AM
To: Kim Schmelzer
Subject: RE: Please Confirm

Hello Kim,

(b)(4)

Sincerely,
Stacie Gutowski, Ph.D.
Biomedical Engineer
ODE/DNPMD/NSDB
WO 66, Rm 2656
10903 New Hampshire Avenue
Silver Spring, MD 20993
(240) 402-6032
Stacie.Gutowski@fda.hhs.gov

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https://www.research.net/s/cdrhcustomerservice?O=400&D=460&B=462&E=&S=E

From: Kim Schmelzer [mailto:(b)(6)
Sent: Wednesday, June 22, 2016 4:57 PM
To: Gutowski, Stacie
Cc: (b)(6)
Subject: Please Confirm

Stacie,

(b)(4)

Thank you,
Kim Schmelzer | Quality Manager
PMT Corporation | Permark
1500 Park Road Chanhassen MN 55317 USA
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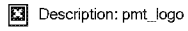
Description: pmt_logo

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Dear Ms. Schmelzer,
Thank you for your email. The review team is looking over your questions and we should have a response for you within a day or two.

Sincerely,
Stacie Gutowski, Ph.D.
Biomedical Engineer
ODE/DNPMD/NSDB
WO 66, Rm 2656
10903 New Hampshire Avenue
Silver Spring, MD 20993
(240) 402-6032
Stacie.Gutowski@fda.hhs.gov

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https://www.research.net/s/cdrhcustomerservice?O=400&D=460&B=462&E=&S=E

From: Kim Schmelzer [mailto:(b)(6)
Sent: Monday, March 07, 2016 3:32 PM
To: Gutowski, Stacie
Subject: RE: K151790/S001 Question
Importance: High

Stacie,

(b)(4)

Thank you,
Kim Schmelzer | Quality Manager
PMT Corporation | Permark
1500 Park Road Chanhassen MN 55317 USA
D: +952.470.0866 | F: +952.470.0865
www.pmtcorp.com | www.permark.com

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From: Gutowski, Stacie [mailto:Stacie.Gutowski@fda.hhs.gov]
Sent: Monday, March 07, 2016 1:17 PM
To: Kim Schmelzer
Cc: k151790@docs.fda.gov
Subject: RE: K151790/S001 Question

Dear Ms. Schmelzer,
Thank you for your email! (b)(4)

(b)(4)

(b)(4) Please let me know if you have any further questions regarding this information.

Sincerely,
Stacie Gutowski, Ph.D.
Biomedical Engineer
ODE/DNPMD/NSDB
WO 66, Rm 2656
10903 New Hampshire Avenue

Records processed under FOIA Request 2024-2207; Released by CDRH on 11-13-2024

Silver Spring, MD 20993
(240) 402-6032
Stacie.Gutowski@fda.hhs.gov

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https://www.research.net/s/cdrhcustomerservice?O=400&D=460&B=462&E=&S=E

From: Kim Schmelzer [mailto (b)(6)
Sent: Wednesday, March 02, 2016 2:51 PM
To: Gutowski, Stacie
Subject: RE: K151790/S001 Question

Stacie,

I hope this email finds you well.

(b)(4)

Thank you,
Kim Schmelzer | Quality Manager
PMT Corporation | Permark
1500 Park Road Chanhassen MN 55317 USA
D: +952.470.0866 | F: +952.470.0865
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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2024-2207; Released by CDRH on 11-13-2024

From: Kim Schmelzer [mailto (b)(6)
Sent: Friday, July 01, 2016 9:17 AM
To: Gutowski, Stacie
Cc: (b)(6)
Subject: FW: Procedures

Stacie,

(b)(4)

(b)(4) Please let me know if you have any questions.

Thank you,
Kim Schmelzer | Quality Manager
PMT Corporation | Permark
1500 Park Road Chanhassen MN 55317 USA
D: +952.470.0866 | F: +952.470.0865
www.pmtcorp.com | www.permark.com

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(b)(4) Label

(b)(4)

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

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(b)(4) Label

(b)(4)

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

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(b)(4) Label

(b)(4)

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

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(b)(4)

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

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(b)(4) Label (b)(4)

(b)(4)

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

Records processed under FOIA Request 2024-2207; Released by CDRH on 11-13-2024

(b)(4) Label (b)(4)

(b)(4)

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

Records processed under FOIA Request 2024-2207; Released by CDRH on 11-13-2024

From: Kim Schmelzer [mailto: (b)(6)

Sent: Friday, July 01, 2016 9:17 AM

To: Gutowski, Stacie

Cc: (b)(6)

Subject: FW: Procedures

Stacie,

(b)(4)

(b)(4) Please let me know if you have any questions.

Thank you,

Kim Schmelzer | Quality Manager

PMT Corporation | Permark

1500 Park Road Chanhassen MN 55317 USA

D: +952.470.0866 | F: +952.470.0865

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PMT® Corporation

CE 0120

INSTRUCTION MANUAL

(b)(4)

Depthalon® Depth Electrode System

(b)(4)

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Hello Kim,

Please see the interactive deficiencies below regarding your (b)(4)
Please keep in mind that we are actively reviewing your file and we may contact you for additional information in the coming days. As before, please respond to these deficiencies direct to me via email, and be sure to cc the document email box (K151790@docs.fda.gov<mailto:K151790@docs.fda.gov>). Please respond by 8am (eastern time) on Wednesday June 29, 2016. Let me know if you have any questions.

(b)(4)

Sincerely,

Stacie Gutowski, Ph.D.

Biomedical Engineer

ODE/DNPMD/NSDB

WO 66, Rm 2656

10903 New Hampshire Avenue

Silver Spring, MD 20993

(240) 402-6032

Stacie.Gutowski@fda.hhs.gov<mailto:Stacie.Gutowski@fda.hhs.gov>

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From: Kim Schmelzer [mailto:(b)(6)

Sent: Thursday, June 23, 2016 11:00 AM

To: Gutowski, Stacie

Subject: RE: Please Confirm

Stacie,

(b)(4)

Thank you,

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

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Kim Schmelzer | Quality Manager

PMT Corporation | Permark

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D: +952.470.0866 | F: +952.470.0865

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From: Gutowski, Stacie [mailto:Stacie.Gutowski@fda.hhs.gov]

Sent: Thursday, June 23, 2016 8:36 AM

To: Kim Schmelzer

Subject: RE: Please Confirm

Hello Kim,

(b)(4)

Sincerely,

Stacie Gutowski, Ph.D.

Biomedical Engineer

ODE/DNPMD/NSDB

WO 66, Rm 2656

10903 New Hampshire Avenue

Silver Spring, MD 20993

(240) 402-6032

Stacie.Gutowski@fda.hhs.gov<mailto:Stacie.Gutowski@fda.hhs.gov>

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From: Kim Schmelzer [mailto: **(b)(6)**

Sent: Wednesday, June 22, 2016 4:57 PM

To: Gutowski, Stacie

Cc: **(b)(6)** <mailto: **(b)(6)**

Subject: Please Confirm

Stacie,

(b)(4)

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

Thank you,

Kim Schmelzer | Quality Manager

PMT Corporation | Permark

1500 Park Road Chanhassen MN 55317 USA

D: +952.470.0866 | F: +952.470.0865

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ORIGINAL

PMT CORPORATION

Document type: *Technical Report*	Document No. (b)(4)	Page 1 of 4
Document title: (b)(4)	Effective Date 08/15/09	Current Rev. (b)(4)

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

Form Approval
OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on page 5.

Date of Submission	User Fee Payment ID Number	FDA Submission Document Number *(if known)*
	(b)(4)	

SECTION A TYPE OF SUBMISSION

PMA	PMA & HDE Supplement	PDP	510(k)	Request for Feedback
☐ Original Submission	☐ Regular (180 day)	☐ Original PDP	☒ Original Submission:	☐ Pre-Submission
☐ Premarket Report	☐ Special	☐ Notice of Completion	☒ Traditional	☐ Informational Meeting
☐ Modular Submission	☐ Panel Track (PMA Only)	☐ Amendment to PDP	☐ Special	☐ Submision Issue Meeting
☐ Amendment	☐ 30-day Supplement		☐ Abbreviated (Complete section I, Page 5)	☐ Day 100 Meeting
☐ Report	☐ 30-day Notice		☐ Additional Information	☐ Agreement Meeting
☐ Report Amendment	☐ 135-day Supplement		☐ Third Party	☐ Determination Meeting
☐ Licensing Agreement	☐ Real-time Review			☐ Study Risk Determination
	☐ Amendment to PMA & HDE Supplement			☐ Other *(specify)*:
	☐ Other			

IDE	Humanitarian Device Exemption (HDE)	Class II Exemption Petition	Evaluation of Automatic Class III Designation (De Novo)	Other Submission
☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ 513(g)
☐ Amendment	☐ Amendment	☐ Additional Information	☐ Additional Information	☐ Other *(describe submission)*:
☐ Supplement	☐ Supplement			
	☐ Report			
	☐ Report Amendment			

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

SECTION B SUBMITTER, APPLICANT OR SPONSOR

Company / Institution Name	Establishment Registration Number *(if known)*		
PMT Corporation	2182979		
Division Name *(if applicable)*	**Phone Number *(including area code)***		
	952-470-0866		
Street Address	**FAX Number *(including area code)***		
1500 Park Road	952-470-0865		
City	**State / Province**	**ZIP/Postal Code**	**Country**
Chanhassen	MN	55317	US
Contact Name			
Kim Schmelzer			
Contact Title	**Contact E-mail Address**		
Quality Manager	(b)(6)		

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

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

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SECTION D1 REASON FOR APPLICATION - PMA, PDP, OR HDE

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

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

- ☐ Location change:
  - ☐ Manufacturer
  - ☐ Sterilizer
  - ☐ Packager

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

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

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

- ☐ Response to FDA correspondence:

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

- ☐ Other Reason *(specify)*:

SECTION D2 REASON FOR APPLICATION - IDE

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

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

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

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

- ☐ Other Reason *(specify)*:

SECTION D3 REASON FOR SUBMISSION - 510(k)

- ☐ New Device
- ☒ Additional or Expanded Indications
- ☐ Change in Technology

- ☐ Other Reason *(specify)*:

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

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SECTION E ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed

1	GZL	2		3		4	
5		6		7		8	

Summary of, or statement concerning, safety and effectiveness information

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

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

	510(k) Number		*Trade or Proprietary or Model Name*		*Manufacturer*
1	K082152	1	PMT Depthalon Depth Electrode Model 2102	1	PMT Corporation
2	K041604	2	Macro-Micro Electrodes	2	Ad-tech Corporation
3		3		3	
4		4		4	
5		5		5	
6		6		6	

SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification name

PMT Platinum Depthalon Depth Electrodes

	Trade or Proprietary or Model Name for This Device	Model Number
1	(b)(4)	
2		
3		
4		
5		5

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

1 K082152	2	3	4	5	6
7	8	9	10	11	12

Data Included in Submission

☒ Laboratory Testing ☐ Animal Trials ☐ Human Trials

SECTION G PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS

Product Code	C.F.R. Section *(if applicable)*	Device Class
GZL	882.1330	☐ Class I ☒ Class II
Classification Panel		☐ Class III ☐ Unclassified
Neurology		

Indications *(from labeling)*

(b)(4)

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

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Note: Submission of the information entered in Section H does not affect the need to submit device establishment registration.	FDA Document Number *(if known)*

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

(b)(4)

☐ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☐ Manufacturer ☐ Contract Manufacturer ☐ Contract Sterilizer ☐ Repackager / Relabeler		
Company / Institution Name		Establishment Registration Number		
Division Name *(if applicable)*		Phone Number *(including area code)*		
Street Address		FAX Number *(including area code)*		
City		State / Province	ZIP Code	Country
Contact Name	Contact Title		Contact E-mail Address	

☐ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☐ Manufacturer ☐ Contract Manufacturer ☐ Contract Sterilizer ☐ Repackager / Relabeler		
Company / Institution Name		Establishment Registration Number		
Division Name *(if applicable)*		Phone Number *(including area code)*		
Street Address		FAX Number *(including area code)*		
City		State / Province	ZIP Code	Country
Contact Name	Contact Title		Contact E-mail Address	

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

Records processed under UTILIZATION OF STANDARDS by CDRH on 11-15-2024

SECTION I

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

	Standards No.	Standards Organization	Standards Title	Version	Date
1	CFR Title 21 Part 820	FDA	Quality System Regulations	Current	
2	ISO 13485:2003	ISO	Quality System - Medical Device Particular Requirements for Application of 9001	2003	
3	BS/EN/ISO 14971:2012	ISO	Medical Devices - Application of Risk Management	2012	
4	(b)(4)			2012	
5	IEC 60601-1 (b)(4)	IEC	Medical Electrical Equipment Part 1: General Requirements for basic Safety and Essential Performance	3rd	
6	CFR Title 21 Part 898	FDA	Performance Standard for Electrode Lead Wire and Patient Cables		
7			SEE ATTACHED SHEET FOR ADDITIONAL STANDARDS		

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

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PMT Corporation
510(k) Summary

510(k) Number: K151790

I certify that, in my capacity as Quality Manager of PMT Corporation, I will make available all information included in this premarket notification on safety and effectiveness within 30 days of request by any person if the device described in the premarket notification submission is determined to be substantially equivalent. The information I agree to make available will be a duplicate of the premarket notification submission, including any adverse safety and effectiveness information, but excluding all patient identifiers, and trade secret and confidential commercial information, as defined in 21 CFR 20.61.

(b)(6)

Date: 6/22/16

Kim Schmelzer
Quality Manager
PMT Corporation

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

(b)(4) Records processed under FOIA Request 2024-2207; Released by CDRH on 11-13-2024

From: Kim Schmelzer [mailto: (b)(6)

Sent: Monday, July 11, 2016 8:56 AM

To: Gutowski, Stacie

Subject: RE: (b)(4) needed for K151790

Stacie,

(b)(4)

Thank you,

Kim Schmelzer | Quality Manager

PMT Corporation | Permark

1500 Park Road Chanhassen MN 55317 USA

D: +952.470.0866 | F: +952.470.0865

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From: Gutowski, Stacie [mailto:Stacie.Gutowski@fda.hhs.gov]

Sent: Monday, July 11, 2016 6:52 AM

To: Kim Schmelzer

Subject: RE: (b)(4) needed for K151790

Hello Kim,

(b)(4)

Sincerely,

Stacie Gutowski, Ph.D.

Biomedical Engineer

ODE/DNPMD/NSDB

WO 66, Rm 2656

10903 New Hampshire Avenue

Silver Spring, MD 20993

(240) 402-6032

Stacie.Gutowski@fda.hhs.gov<mailto:Stacie.Gutowski@fda.hhs.gov>

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From: Kim Schmelzer [mailto:(b)(6)

Sent: Friday, July 08, 2016 4:58 PM

To: Gutowski, Stacie

Cc: (b)(6) <mailto:(b)(6)>

Subject: RE: (b)(4) needed for K151790

Stacie,

(b)(4)

(b)(4) Have a wonderful weekend.

Thank you,

Kim Schmelzer | Quality Manager

PMT Corporation | Permark

1500 Park Road Chanhassen MN 55317 USA

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From: Gutowski, Stacie [mailto:Stacie.Gutowski@fda.hhs.gov]

Sent: Friday, July 08, 2016 2:15 PM

To: Kim Schmelzer

Cc: k151790@docs.fda.gov<mailto:k151790@docs.fda.gov>

Subject: RE: (b)(4) needed for K151790

Hi Kim,

(b)(4)

Stacie Gutowski, Ph.D.

Biomedical Engineer

ODE/DNPMD/NSDB

WO 66, Rm 2656

10903 New Hampshire Avenue

Silver Spring, MD 20993

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Stacie.Gutowski@fda.hhs.gov<mailto:Stacie.Gutowski@fda.hhs.gov>

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From: Kim Schmelzer [mailto:(b)(6)

Sent: Thursday, July 07, 2016 9:54 AM

To: Gutowski, Stacie

Subject: RE: (b)(4) needed for K151790

Stacie,

(b)(4)

Thank you,

Kim Schmelzer | Quality Manager

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From: Gutowski, Stacie [mailto:Stacie.Gutowski@fda.hhs.gov]

Sent: Thursday, July 07, 2016 6:42 AM

To: Kim Schmelzer

Cc: k151790@docs.fda.gov<mailto:k151790@docs.fda.gov>

Subject: RE: (b)(4) needed for K151790

Hi Kim,

(b)(4)

Stacie Gutowski, Ph.D.

Biomedical Engineer

ODE/DNPMD/NSDB

WO 66, Rm 2656

10903 New Hampshire Avenue

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

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Stacie.Gutowski@fda.hhs.gov<mailto:Stacie.Gutowski@fda.hhs.gov>

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From: Kim Schmelzer [mailto: (b)(6)

Sent: Wednesday, July 06, 2016 4:55 PM

To: Gutowski, Stacie

Cc: (b)(6) <mailto (b)(6) >

Subject: RE: (b)(4) needed for K151790

Stacie,

(b)(4)

Let me know if you have any further questions on this.

Thank you,

Kim Schmelzer | Quality Manager

PMT Corporation | Permark

1500 Park Road Chanhassen MN 55317 USA

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From: Gutowski, Stacie [mailto:Stacie.Gutowski@fda.hhs.gov]

Sent: Wednesday, July 06, 2016 12:20 PM

To: Kim Schmelzer

Subject: RE: (b)(4) needed for K151790

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

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Hello Kim,

(b)(4)

Stacie Gutowski, Ph.D.

Biomedical Engineer

ODE/DNPMD/NSDB

WO 66, Rm 2656

10903 New Hampshire Avenue

Silver Spring, MD 20993

(240) 402-6032

Stacie.Gutowski@fda.hhs.gov<mailto:Stacie.Gutowski@fda.hhs.gov>

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From: Kim Schmelzer [mailto:(b)(6)

Sent: Wednesday, July 06, 2016 12:05 PM

To: Gutowski, Stacie

Subject: RE: (b)(4) needed for K151790

Stacie,

(b)(4) What further information do you need?

Thank you,

Kim Schmelzer | Quality Manager

PMT Corporation | Permark

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

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From: Gutowski, Stacie [mailto:Stacie.Gutowski@fda.hhs.gov]

Sent: Wednesday, July 06, 2016 10:12 AM

To: Kim Schmelzer

Cc: k151790@docs.fda.gov<mailto:k151790@docs.fda.gov>

Subject: (b)(4) needed for K151790

Hello Kim,

(b)(4)

Stacie Gutowski, Ph.D.

Biomedical Engineer

ODE/DNPMD/NSDB

WO 66, Rm 2656

10903 New Hampshire Avenue

Silver Spring, MD 20993

(240) 402-6032

Stacie.Gutowski@fda.hhs.gov<mailto:Stacie.Gutowski@fda.hhs.gov>

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

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From: Kimberly Schmelzer (b)(6)

Sent: Thursday, June 16, 2016 2:35 PM

To: Gutowski, Stacie

Subject: RE: FDA requesting teleconference with your team

(b)(4)

Kim Schmelzer

Kim Schmelzer Sent from Mail for Windows 10

From: Gutowski, Stacie<mailto:Stacie.Gutowski@fda.hhs.gov>

Sent: Wednesday, June 15, 2016 8:01 PM

To: Ben Osa<mailto:(b)(6)

Cc: k151790@docs.fda.gov<mailto:k151790@docs.fda.gov>; (b)(6) <mailto:(b)(6) (b)(6)

Subject: RE: FDA requesting teleconference with your team

Hello Ben,

Thank you for understanding. The call-in information is below. We look forward to speaking with you at 2pm (eastern) on June 16.

(b)(4)

Stacie Gutowski, Ph.D.

Biomedical Engineer

ODE/DNPMD/NSDB

WO 66, Rm 2656

10903 New Hampshire Avenue

Silver Spring, MD 20993

(240) 402-6032

Stacie.Gutowski@fda.hhs.gov<mailto:Stacie.Gutowski@fda.hhs.gov>

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From: Ben Osa [mailto:(b)(6)

Sent: Wednesday, June 15, 2016 5:29 PM

To: Gutowski, Stacie

Cc: k151790@docs.fda.gov;(b)(6)

Subject: RE: FDA requesting teleconference with your team

Hi Stacie â€" We can do a conference call tomorrow. Is there a dial in # for the call?

(b)(4)

Thanks for your help on this submittal.

- Ben

Benjamin Osa

Neurosurgery Engineering Manager

PMT Corporation

1500 Park Road

Chanhassen, MN 55317

Email:(b)(6)<mailto:(b)(6)>

(P) 952-470-0866

(F) 952-470-0865

From: Gutowski, Stacie [mailto:Stacie.Gutowski@fda.hhs.gov]

Sent: Wednesday, June 15, 2016 3:58 PM

To: Ben Osa

Cc: k151790@docs.fda.gov<mailto:k151790@docs.fda.gov>;
(b)(6)<mailto:(b)(6)

Subject: RE: FDA requesting teleconference with your team

Records processed under FOIA Request 2024-2207; Released by CDRH on 11-13-2024

Hello Ben,

(b)(4)

Stacie Gutowski, Ph.D.

Biomedical Engineer

ODE/DNPMD/NSDB

WO 66, Rm 2656

10903 New Hampshire Avenue

Silver Spring, MD 20993

(240) 402-6032

Stacie.Gutowski@fda.hhs.gov<mailto:Stacie.Gutowski@fda.hhs.gov>

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https://www.research.net/s/cdrhcustomerservice?O=400&D=460&B=462&E=&S=E

From: Ben Osa [mailto:(b)(6)

Sent: Wednesday, June 15, 2016 4:52 PM

To: Gutowski, Stacie

Cc: k151790@docs.fda.gov<mailto:k151790@docs.fda.gov>;
(b)(6) <mailto:(b)(6)

Subject: FDA requesting teleconference with your team

Hi Stacie â€" (b)(6)
(b)(6)

Is there a way we can do a teleconference on that date or a day soon afterwards?

Please let me know.

Thanks,

- Ben

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

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Benjamin Osa

Neurosurgery Engineering Manager

PMT Corporation

1500 Park Road

Chanhassen, MN 55317

Email: (b)(6) <mailto (b)(6)

(P) 952-470-0866

(F) 952-470-0865

From: Gutowski, Stacie [mailto:Stacie.Gutowski@fda.hhs.gov]

Sent: Wednesday, June 15, 2016 1:47 PM

To: Kim Schmelzer

Cc: k151790@docs.fda.gov<mailto:k151790@docs.fda.gov>

Subject: FDA requesting teleconference with your team

Hello Kim,

(b)(4) Can we setup a teleconference meeting with you and your team tomorrow afternoon at 2pm (eastern time)? Please let me know if you are available.

Sincerely,

Stacie Gutowski, Ph.D.

Biomedical Engineer

ODE/DNPMD/NSDB

WO 66, Rm 2656

10903 New Hampshire Avenue

Silver Spring, MD 20993

(240) 402-6032

Stacie.Gutowski@fda.hhs.gov<mailto:Stacie.Gutowski@fda.hhs.gov>

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Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

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

TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ISO 11607-1:2006, Packaging For Terminally Sterilized Medical Devices - Part 1: Requirements For Materials, Sterile Barrier Systems And Packaging Systems

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#14-454	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☒	☐
If yes, was the guidance document followed in preparation of this 510k?	☒	☐

Title of guidance: Premarket Notification [510(K)] Submissions For Medical Sterilization Packaging Systems In Health Care

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

[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

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

[6] The online search for CDRH Guidance Documents can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm

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

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U.S. Food and Drug Administration
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Recognition List Number: 038 **FR Publication Date:** 01/27/2015

Part B: Supplementary Information

Recognition Number 14-454: ISO 11607-1 First Edition 2006-04-15, Packaging For Terminally Sterilized Medical Devices - Part 1: Requirements For Materials, Sterile Barrier Systems And Packaging Systems [Including: Amendment 1 (2014)]. (Sterility)

Date of Standard: 2006.

Address of Standards Development Organization:

International Organization for Standardization (ISO)*
1, Rue de Varembe
Case Postale 56
CH 1211 Geneva 20, 0

SWITZERLAND

CDRH Office and Division associated with recognized standards:

ALL OFFICES AND DIVISIONS IN CDRH

Devices Affected:

All packaging for terminally sterilized medical devices

Processes Affected:

510(k), PMA, PDP, IDE, HDE, Quality System Regulation

Type of Standard:

Horizontal, International

Extent of Recognition:

Complete standard and any annexes.

Relevant Guidance:

ISO 11607-2 First Edition 2006-04-15, Packaging For Terminally Sterilized Medical Devices - Part 2: Validation Requirements For Forming, Sealing And Assembly Processes [Including: Amendment 1 (2014)]

ISO/TS 16775 First Edition 2014-05-15 Packaging For Terminally Sterilized Medical Devices ¿ Guidance On The Application Of ISO 11607-1 And ISO

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

11607-2

Premarket Notification [510(K)] Submissions For Medical Sterilization Packaging Systems In Health Care Facilities; Draft Guidance For Industry And FDA, March 7, 2002

FDA Technical Contact:

Victoria M. Hitchins, Ph.D
FDA/CDRH/OSEL
10903 New Hampshire Avenue Building 64, Room 4072
Silver Spring MD 20993
301/796-0258
email: victoria.hitchins@fda.hhs.gov

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American National Standards Institute (ANSI)*
25 West 43rd Street
4th Floor
New York, NY 10036

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22. /scripts/cdrh/cfdocs/cfTPLC/inspect.cfm

Page Last Updated: 08/05/2013

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22. /scripts/cdrh/cfdocs/cfTPLC/inspect.cfm

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Form Approved: OMB No. 0910-0120; Expiration Date: 1/31/2017

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

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

TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ISO 10993-7:2008 Biological evaluation of medical devices – Part 7: Ethylene oxide sterilization residuals

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#14-408	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

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

[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

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

[6] The online search for CDRH Guidance Documents can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm

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

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Recognized Consensus Standards

CDRH SuperSearch

6 510(k)[7] | DeNovo[8] | Registration & Listing[9] | Adverse Events[10] | Recalls[11] | PMA[12] | HDE[13] | Classification[14] | Standards[15]
CFR Title 21[16] | Radiation-Emitting Products[17] | X-Ray Assembler[18] | Medsun Reports[19] | CLIA[20] | TPLC[21] | Inspections[22]

New Search Back To Search Results

Recognition List Number: 034 **FR Publication Date:** 01/30/2014

Part B: Supplementary Information

Recognition Number 14-408: ISO 10993-7 Second Edition 2008-10-15, Biological Evaluation Of Medical Devices - Part 7: Ethylene Oxide Sterilization Residuals [Including: Technical Corrigendum 1 (2009)]. (Sterility)

Date of Standard: 2008.

Address of Standards Development Organization:

International Organization for Standardization (ISO)*
1, Rue de Varembe
Case Postale 56
CH 1211 Geneva 20, 0

SWITZERLAND

CDRH Office and Division associated with recognized standards:

ALL OFFICES AND DIVISIONS IN CDRH

Devices Affected:

All devices subjected to ethylene oxide sterilization

Processes Affected:

510(k), IDE, PMA, PDP, HDE, Quality System Regulation

Type of Standard:

Horizontal, International

Extent of Recognition:

Complete standard and any annexes.

FDA Technical Contact:

Anne D. Lucas
FDA/CDRH/OSEL
10903 New Hampshire Avenue Building 64, Room 4010
Silver Spring MD 20993
301/796-0283
email: anne.lucas@fda.hhs.gov

*** In the United States, copies of this standard can be obtained from:**
American National Standards Institute (ANSI)*

25 West 43rd Street
4th Floor
New York, NY 10036

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6. /scripts/cdrh/devicesatfda/index.cfm
7. /scripts/cdrh/cfdocs/cfPMN/pmn.cfm
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10. /scripts/cdrh/cfdocs/cfMAUDE/TextSearch.cfm
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19. /scripts/cdrh/cfdocs/Medsun/searchReportText.cfm
20. /scripts/cdrh/cfdocs/cfClia/Search.cfm
21. /scripts/cdrh/cfdocs/cfTPLC/tplc.cfm
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Contact FDA

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5. http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Databases/default.htm
6. /scripts/cdrh/devicesatfda/index.cfm
7. /scripts/cdrh/cfdocs/cfPMN/pmn.cfm
8. /scripts/cdrh/cfdocs/cfpmn/denovo.cfm
9. /scripts/cdrh/cfdocs/cfRL/rl.cfm
10. /scripts/cdrh/cfdocs/cfMAUDE/TextSearch.cfm
11. /scripts/cdrh/cfdocs/cfRES/res.cfm
12. /scripts/cdrh/cfdocs/cfPMA/pma.cfm
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18. /scripts/cdrh/cfdocs/cfAssem/assembler.cfm
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Form Approved: OMB No. 0910-0120; Expiration Date: 1/31/2017

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ANSI / AAMI / ISO 11135-1:2007 – Validation and routine control of ethylene oxide sterilization

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#14-452	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

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

[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

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

Recognized Consensus Standards

Recognition List Number: 036 **FR Publication Date:** 07/09/2014

Part B: Supplementary Information

Recognition Number 14-452: ISO 11135 Second Edition 2014, Sterilization Of Health-Care Products ¿ Ethylene Oxide - Requirements For The Development, Validation And Routine Control Of A Sterilization Process For Medical Devices. (Sterility)

Date of Standard: 2014.

Address of Standards Development Organization:

International Organization for Standardization (ISO)*
1, Rue de Varembe
Case Postale 56
CH 1211 Geneva 20, 0

SWITZERLAND

CDRH Office and Division associated with recognized standards:

ALL OFFICES AND DIVISIONS IN CDRH

Devices Affected:

All devices subjected to ethylene oxide sterilization

Processes Affected:

510(k), IDE, PMA, PDP, HDE, Quality System Regulation, Manufacturing, Sterilization, Packaging

Type of Standard:

Horizontal, International

Extent of Recognition:

Complete standard and any annexes except for sections referencing ISO 13485:2003. FDA requires medical device manufacturers to comply with the Code of Federal Regulations (CFR), 21 CFR Part 820 Quality System Regulation and therefore does not require compliance with ISO 13485 for the establishment of a Quality Management System.

Relevant Guidance:

AAMI TIR 14:2009, Contract Sterilization Using Ethylene Oxide

AAMI TIR 15:2009 (R2013), Physical Aspects Of Ethylene Oxide Sterilization

AAMI TIR 16:2009 (R2013), Microbiological Aspects Of Ethylene Oxide Sterilization

AAMI TIR 17:2008, Compatibility Of Materials Subject To Sterilization

AAMI TIR 28:2009 (R2013), Product Adoption And Process Equivalence For Ethylene Oxide Sterilization

FDA Technical Contacts:

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Maitland FL 32751
407/475-4700
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salvatore.randazzo@fda.hhs.gov

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New York, NY 10036

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

Form Approval
OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on page 5.

Date of Submission	User Fee Payment ID Number	FDA Submission Document Number *(if known)*
	(b)(4)	

SECTION A TYPE OF SUBMISSION

PMA	PMA & HDE Supplement	PDP	510(k)	Request for Feedback
☐ Original Submission	☐ Regular (180 day)	☐ Original PDP	☒ Original Submission:	☐ Pre-Submission
☐ Premarket Report	☐ Special	☐ Notice of Completion	☒ Traditional	☐ Informational Meeting
☐ Modular Submission	☐ Panel Track (PMA Only)	☐ Amendment to PDP	☐ Special	☐ Submision Issue Meeting
☐ Amendment	☐ 30-day Supplement		☐ Abbreviated (Complete section I, Page 5)	☐ Day 100 Meeting
☐ Report	☐ 30-day Notice		☐ Additional Information	☐ Agreement Meeting
☐ Report Amendment	☐ 135-day Supplement		☐ Third Party	☐ Determination Meeting
☐ Licensing Agreement	☐ Real-time Review			☐ Study Risk Determination
	☐ Amendment to PMA & HDE Supplement			☐ Other *(specify)*:
	☐ Other			

IDE	Humanitarian Device Exemption (HDE)	Class II Exemption Petition	Evaluation of Automatic Class III Designation (De Novo)	Other Submission
☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ 513(g)
☐ Amendment	☐ Amendment	☐ Additional Information	☐ Additional Information	☐ Other *(describe submission)*:
☐ Supplement	☐ Supplement			
	☐ Report			
	☐ Report Amendment			

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

SECTION B SUBMITTER, APPLICANT OR SPONSOR

Company / Institution Name	Establishment Registration Number *(if known)*		
PMT Corporation	2182979		
Division Name *(if applicable)*	**Phone Number** *(including area code)*		
	952-470-0866		
Street Address	**FAX Number** *(including area code)*		
1500 Park Road	952-470-0866		
City	**State / Province**	**ZIP/Postal Code**	**Country**
Chanhassen	MN	55317	USA
Contact Name			
Kim Schmelzer			
Contact Title	**Contact E-mail Address**		
Quality Manager	(b)(6)		

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

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

PSC Publishing Services (301) 443-6740 EF

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

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SECTION D1 REASON FOR APPLICATION - PMA, PDP, OR HDE

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

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

- ☐ Response to FDA correspondence:

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

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

- ☐ Location change:
  - ☐ Manufacturer
  - ☐ Sterilizer
  - ☐ Packager

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

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

☐ Other Reason *(specify)*:

SECTION D2 REASON FOR APPLICATION - IDE

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

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

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

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

☐ Other Reason *(specify)*:

SECTION D3 REASON FOR SUBMISSION - 510(k)

- ☐ New Device
- ☒ Additional or Expanded Indications
- ☐ Change in Technology

☐ Other Reason *(specify)*:

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

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SECTION E ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed

1	GZL	2		3		4	
5		6		7		8	

Summary of, or statement concerning, safety and effectiveness information

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

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

	510(k) Number	*Trade or Proprietary or Model Name*	*Manufacturer*
1	K082152	PMT Depthalon Depth Electrode Model 2102	PMT Corporation
2	K041604	Macro-Micro Electrodes	Ad-tech Corporation
3			
4			
5			
6			

SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification name

Depth Electrode, Macro Depth Electrodes, Micro Depth Electrodes, Microwire Depth Electrodes, Macro-Micro Depth Electrodes, Macro-Microwire Depth Electrodes, sEEG Depth Electrodes, Accunav Depth Electrodes

	Trade or Proprietary or Model Name for This Device	Model Number
1	Depthalon Depth Electrode	(b)(4)
2	(b)(4)	
3		
4		
5		

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

1 K082152	2	3	4	5	6
7	8	9	10	11	12

Data Included in Submission

☒ Laboratory Testing ☐ Animal Trials ☐ Human Trials

SECTION G PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS

Product Code	C.F.R. Section *(if applicable)*	Device Class
GZL	882.1330	☐ Class I ☒ Class II
Classification Panel		☐ Class III ☐ Unclassified
Neurology		

Indications *(from labeling)*

(b)(4)

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

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Note: Submission of the information entered in Section H does not affect the need to submit device establishment registration.	FDA Document Number *(if known)*

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

(b)(4)

☐ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☐ Manufacturer ☐ Contract Manufacturer	☐ Contract Sterilizer ☐ Repackager / Relabeler
Company / Institution Name		Establishment Registration Number	
Division Name *(if applicable)*		Phone Number *(including area code)*	
Street Address		FAX Number *(including area code)*	
City		State / Province	ZIP Code / Country
Contact Name	Contact Title	Contact E-mail Address	

☐ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☐ Manufacturer ☐ Contract Manufacturer	☐ Contract Sterilizer ☐ Repackager / Relabeler
Company / Institution Name		Establishment Registration Number	
Division Name *(if applicable)*		Phone Number *(including area code)*	
Street Address		FAX Number *(including area code)*	
City		State / Province	ZIP Code / Country
Contact Name	Contact Title	Contact E-mail Address	

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

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SECTION I — UTILIZATION OF STANDARDS

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

	Standards No.	Standards Organization	Standards Title	Version	Date
1	CFR Title 21 Part 820	FDA	Quality System Regulations	Current	
2	ISO 13485:2003	ISO	Quality System - Medical Device Particular Requirements for Application of 9001	2003	
3	BS/EN/ISO 14971:2012	ISO	Medical Devices - Application of Risk Management	2012	
4	(b)(4)				
5	IEC 60601-1 (b)(4)	IEC	Medical Electrical Equipment Part 1: General Requirements for basic Safety and Essential Performance	3rd	
6	CFR Title 21 Part 898	FDA	Performance Standard for Electrode Lead Wire and Patient Cables		
7			SEE ATTACHED SHEET FOR ADDITIONAL STANDARDS		

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

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Dear Ms. Schmelzer,

Please find our responses to your questions below.

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(b)(4)

Sincerely,

Stacie Gutowski, Ph.D.

Biomedical Engineer

ODE/DNPMD/NSDB

WO 66, Rm 2656

10903 New Hampshire Avenue

Silver Spring, MD 20993

(240) 402-6032

Stacie.Gutowski@fda.hhs.gov<mailto:Stacie.Gutowski@fda.hhs.gov>

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From: Kim Schmelzer [mailto: (b)(6)

Sent: Monday, March 07, 2016 3:32 PM

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To: Gutowski, Stacie

Subject: RE: K151790/S001 Question

Importance: High

Stacie,

Thank you for your reply. I do have a couple questions.

(b)(4)

Thank you,

Kim Schmelzer | Quality Manager

PMT Corporation | Permark

1500 Park Road Chanhassen MN 55317 USA

D: +952.470.0866 | F: +952.470.0865

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From: Gutowski, Stacie [mailto:Stacie.Gutowski@fda.hhs.gov]

Sent: Monday, March 07, 2016 1:17 PM

To: Kim Schmelzer

Cc: k151790@docs.fda.gov<mailto:k151790@docs.fda.gov>

Subject: RE: K151790/S001 Question

Dear Ms. Schmelzer,

Thank you for your email. (b)(4)

(b)(4)

(b)(4) Please let me know if you have any further questions regarding this information.

Sincerely,

Stacie Gutowski, Ph.D.

Biomedical Engineer

ODE/DNPMD/NSDB

WO 66, Rm 2656

10903 New Hampshire Avenue

Silver Spring, MD 20993

(240) 402-6032

Stacie.Gutowski@fda.hhs.gov<mailto:Stacie.Gutowski@fda.hhs.gov>

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From: Kim Schmelzer [mailto: (b)(6)

Sent: Wednesday, March 02, 2016 2:51 PM

To: Gutowski, Stacie

Subject: RE: K151790/S001 Question

Stacie,

I hope this email finds you well.

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Thank you,

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From: Kim Schmelzer [mailto:(b)(6)

Sent: Wednesday, June 22, 2016 5:15 PM

To: Gutowski, Stacie

Cc: (b)(6)

Subject: (b)(4)

Stacie,

(b)(4)

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

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Thank you,

Kim Schmelzer | Quality Manager

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PMT CORPORATION		ORIGINAL
Document type: MANUFACTURING PROCEDURE	Document No. (b)(4)	Page 1 of 13
Document title: (b)(4)	Effective Date 4/30/12	Current Rev. (b)(4)

(b)(4)

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Department of Health & Human Services **Food and Drug Administration**

MEMORANDUM

Hyung-yul Lee -S
2016.07.12 08:49:27 -04'00'

Date: July 12, 2016

To: Stacie Gutowski, PhD
Team Leader
DNPMD/NSDB

From: Hyung Lee, PhD
Sterility Reviewer
DNPMD/NSDB

Cc: The Record

Device Name: Platinum Depthalon® Depth Electrodes (Macro Depth Electrodes, Micro Depth Electrodes, sEEG Depth Electrodes, AccuNav® Depth Electrodes)

Sponsor: PMT, Corp.

Re: Sponsor's Responses to Clearance for Depthalon® Depth Electrodes

(b)(5)

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

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Indications for Use Statement

510(k) Number (if known): K151790

Device Name

PMT® Platinum Depthalon® Depth Electrodes

Indications for Use

The Platinum Depthalon® Depth Electrodes are intended for temporary (<30 day) use with recording, monitoring, and stimulation equipment for the recording, monitoring and stimulation of electrical signals in the subsurface of the brain.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use __X___ OR Over the Counter Use_____
(Per 21 CFR 801.109

(Optimal Format 1-2-96)

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

Records processed under FOIA Request 2024-2207; Released by CDRH on 11-13-2024

Dear Kim,

Thank you for the additional information. We will incorporate this into our review.

Sincerely,

Stacie Gutowski, Ph.D.

Biomedical Engineer

ODE/DNPMD/NSDB

WO 66, Rm 2656

10903 New Hampshire Avenue

Silver Spring, MD 20993

(240) 402-6032

Stacie.Gutowski@fda.hhs.gov<mailto:Stacie.Gutowski@fda.hhs.gov>

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https://www.research.net/s/cdrhcustomerservice?O=400&D=460&B=462&E=&S=E

From: Kim Schmelzer [mailto: (b)(6)

Sent: Monday, October 19, 2015 5:04 PM

To: Gutowski, Stacie

Subject: RE: K151790/S001 Follow-up Information Request

Staci,

I hope you had a good weekend!

(b)(4)

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

Records processed under FOIA Request 2024-2207; Released by CDRH on 11-13-2024

(b)(4)

Let me know if you have any further questions or concerns.

Thank you,

Kim Schmelzer | Quality Manager

PMT Corporation | Permark

1500 Park Road Chanhassen MN 55317 USA

D: +952.470.0866 | F: +952.470.0865

Toll Free: 1.800.MANKIND (626-5463)

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From: Gutowski, Stacie [mailto:Stacie.Gutowski@fda.hhs.gov]

Sent: Friday, October 16, 2015 7:56 AM

To: Kim Schmelzer

Cc: k151790@docs.fda.gov<mailto:k151790@docs.fda.gov>

Subject: RE: K151790/S001 Follow-up Information Request

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

Records processed under FOIA Request 2024-2207; Released by CDRH on 11-13-2024

Dear Ms. Schmelzer,

Thank you for following up with the requested information. (b)(4)

(b)(4)

Please let me know if you have any questions.

Stacie Gutowski, Ph.D.

Biomedical Engineer

ODE/DNPMD/NSDB

WO 66, Rm 2656

10903 New Hampshire Avenue

Silver Spring, MD 20993

(240) 402-6032

Stacie.Gutowski@fda.hhs.gov<mailto:Stacie.Gutowski@fda.hhs.gov>

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https://www.research.net/s/cdrhcustomerservice?O=400&D=460&B=462&E=&S=E

From: Kim Schmelzer [mailto: (b)(6)

Sent: Wednesday, October 14, 2015 2:15 PM

To: Gutowski, Stacie

Cc: k151790@docs.fda.gov<mailto:k151790@docs.fda.gov>

Subject: RE: K151790/S001 Follow-up Information Request

Stacie,

(b)(4)

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

Let me know if you have any questions or need clarification.

Thank you,

Kim Schmelzer | Quality Manager

PMT Corporation | Permark

1500 Park Road Chanhassen MN 55317 USA

D: +952.470.0866 | F: +952.470.0865

Toll Free: 1.800.MANKIND (626-5463)

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From: Gutowski, Stacie [mailto:Stacie.Gutowski@fda.hhs.gov]

Sent: Wednesday, October 14, 2015 11:38 AM

To: (b)(6) <mailto:(b)(6)>

Cc: k151790@docs.fda.gov<mailto:k151790@docs.fda.gov>

Subject: K151790/S001 Follow-up Information Request

Ms. Schmelzer,

We have completed administrative review of your submission (K151790) and have accepted the file for substantive review. (b)(4)
(b)(4)
(b)(4) Please email me with the updated documents, and be sure to cc the docs.fda.gov email address above on all future communications for this file. You only need to send the documentation for the items requested, no need to send the whole submission again.

Please let me know if you have any questions.

Stacie Gutowski, Ph.D.

Biomedical Engineer

ODE/DNPMD/NSDB

WO 66, Rm 2656

10903 New Hampshire Avenue

Silver Spring, MD 20993

(240) 402-6032

Stacie.Gutowski@fda.hhs.gov<mailto:Stacie.Gutowski@fda.hhs.gov>

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https://www.research.net/s/cdrhcustomerservice?O=400&D=460&B=462&E=&S=E

From: Stacie Gutowski [mailto:stacie.gutowski@fda.hhs.gov]

Records processed under FOIA Request 2024-2207; Released by CDRH on 11-13-2024

Sent: Wednesday, October 14, 2015 11:50 AM

To: (b)(6) <mailto: (b)(6) >

Cc: Gutowski, Stacie

Subject: K151790/S001 was Accepted

October 14, 2015

Acceptance Review Notification - Accepted

An administrative acceptance review was conducted on your premarket notification (510(k)) K151790/S001, and it was found to contain all of the necessary elements and information needed to proceed with the substantive review. We will contact you should we require any additional information during the course of the substantive review. The lead reviewer assigned to your submission is Stacie Gutowski.

*** This is a system-generated email notification ***

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

Records processed under FOIA Request 2024-2207; Released by CDRH on 11-13-2024

K151790

FDA/CDRH/DCC
JUL 24 2015
RECEIVED

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July 23, 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

Reference: K151790 – PMT® Depthalon® Depth Electrode (b)(4)

To Whom It May Concern:

Per your letter dated 7/23/2015 received via email. PMT hereby submits this replacement eCopy for the Depthalon Depth Electrode (b)(4) family 510(k) submittal K151790.

This submission contains confidential commercial and trade secret information. We respectfully request that you give this notification the maximum protection provided by law.

Thank you in advance for your consideration of this application. If there are any questions, please contact me at 952-470-0866 or (b)(6)

Sincerely,

(b)(6)

Kim Schmelzer
Quality Manager
PMT Corporation

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

Records processed under FOIA Request 2024-2207; Released by CDRH on 11-13-2024

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K151790

July 21, 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

Reference: K151790 – PMT® Depthalon® Depth Electrode (b)(4)

To Whom It May Concern:

PMT hereby submits this replacement eCopy for the Depthalon Depth Electrode (b)(4) (b)(4) family 510(k) submittal K151790.

This submission contains confidential commercial and trade secret information. We respectfully request that you give this notification the maximum protection provided by law.

Thank you in advance for your consideration of this application. If there are any questions, please contact me at 952-470-0866 or (b)(6)

Sincerely,

(b)(6)

Quality Manager
PMT Corporation

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

Records processed under FOIA Request 2024-2207; Released by CDRH on 11-13-2024

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K151790

FDA CDRH DMC

JUL 01 2015

Received

June 25, 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

Reference: K802152 – PMT® Depthalon® Depth Electrode (b)(4)

To Whom It May Concern:

PMT hereby submits this pre-market notification to modify the indications for use for Depthalon Depth Electrode (b)(4) family PMT manufactures and markets.

This submission contains confidential commercial and trade secret information. We respectfully request that you give this notification the maximum protection provided by law.

Thank you in advance for your consideration of this application. If there are any questions, please contact me at 952-470-0866 or (b)(6)

Attached is a copy of our Medical Device User Fee cover sheet for this submission. The PIN is (b)(4)

Sincerely,

(b)(6)

Kim Schmelzer
Quality Manager
PMT Corporation

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

Records processed under FOIA Request 2024-2207; Released by CDRH on 11-13-2024

From: Noy, Kimhak * [Kimhak.Noy@fda.hhs.gov]
Sent: 7/24/2015 6:00:08 PM
To: (b)(6)
CC: DCCLetters [DCCLetters@fda.hhs.gov]
Subject: K151790 ACK LETTER
Attachments: Acknowledgment%20Letter.pdf

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

Records processed under FOIA Request 2024-2207; Released by CDRH on 11-13-2024

Acknowledgment Letter

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

07/24/2015

KIM SCHMELZER
QUALITY MANAGER
PMT CORPORATION
1500 PARK RD
CHANHASSEN, MN 55317
United States

Dear KIM SCHMELZER:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has received your submission. This submission has been assigned the unique document control number below. Please refer prominently to this number in all future correspondence that relates to this submission. Failure to do so may result in processing delays. If the 'Applicant' identified below is incorrect, please notify the 510(k) Staff immediately at (301) 796-5640.

Submission Number: K151790
Received: 07/24/2015
Applicant: PMT CORPORATION
Device: Depthalon Depth Electrode, (b)(4)
(b)(4)

We will notify you when the processing of your 510(k) has been completed or if any additional information is required. YOU MAY NOT PLACE THIS DEVICE INTO COMMERCIAL DISTRIBUTION UNTIL YOU RECEIVE A LETTER FROM FDA ALLOWING YOU TO DO SO.

If any additional information is required, we will notify you via an Acceptance Review communication, Additional Information (AI) request, and/or Interactive Review communication. For additional information on these types of communication and their effect on the FDA Review Clock (if any), please refer to the following guidance documents:

"FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Goals" at http://www.fda.gov/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm089735.htm.

"Refuse to Accept Policy for 510(k)s" at http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM315014.pdf.

"Types of Communication During the Review of Medical Device Submissions" at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm341918.htm.

When responding to an information request that stops the FDA Review Clock (e.g., an AI request or refuse to accept (RTA) decision), you must submit your complete response with valid electronic copy (eCopy) to the Document Control Center (DCC) at the above address. An incomplete response or a response sent any other way (e.g., to another address or via email) will **not** be considered an official response and will not restart the FDA Review Clock. For more information about FDA's eCopy program, including the new technical standards for an eCopy, refer to the guidance document, "eCopy Program for Medical Device Submissions" at http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM313794.pdf

Record processed under FOIA Request 2024-2207, Released by CDRH on 11-18-2024

To learn more about the overall 510(k) submission process, please refer to our website at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/default.htm.

If you have any procedural or policy questions, please refer to our website at http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm or contact the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041, (301) 796-7100, or *DICE@fda.hhs.gov*.

Sincerely yours,

Marjorie Shulman
Director, 510(k) Program
Premarket Notification (510(k)) Staff
Office of Device Evaluation
Center for Devices and Radiological Health

Records processed under FOIA Request 2024-2207; Released by CDRH on 11-13-2024

(b)(4)

SAFETY DATA SHEET

(b)(4)

Records processed under FOIA Request 2024-2207; Released by CDRH on 11-13-2024

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

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(b)(4)

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(b)(4)

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Records processed under FOIA Request 2024-2107 released by CDRH on 11-13-2024

(b)(4)

MATERIAL SAFETY DATA SHEET

(b)(4)

Records processed under FOIA Request 2024-2207; Released by CDRH on 11-13-2024

(b)(4)

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Records processed under FOIA Request 2024-2207; Released by CDRH on 11-13-2024

(b)(4)

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Records processed under FOIA Request 2024-2207; Released by CDRH on 11-13-2024

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Records processed under FOIA Request 2024-2207; Released by CDRH on 11-13-2024

(b)(4)

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(b)(4)

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(b)(4)

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(b)(4)

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(b)(4)

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(b)(4)

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Records processed under FOIA Request 2024-4220 Released by CDRH on 11-13-2024

(b)(4)

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Records processed under FOIA Request 2024-2204 Released by CDRH on 11-13-2024

(b)(4)

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(b)(4)

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(b)(4)

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Records processed under FOIA Request 2024-2207; Released by CDRH on 11-13-2024

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Records processed under FOIA Request 2024-2207; Released by CDRH on 11-13-2024

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Records processed under FOIA Request 2024-2107; Released by CDRH on 11-13-2024

(b)(4)

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

Freedom of Information Act Request 2015-4207 Released by CDRH on July 11, 2021

Memorandum

Biocompatibility Review

Date:	November 30, 2015
To:	Stacie Gutowski, Ph.D., Lead Reviewer DNPMD/NSDB
From:	Dhanya Williams, M.S. Interdisciplinary Scientist, DNPMD/NNDB
Reviewer Electronic Signature:	
Subject:	K151790/S001
Applicant:	PMT Corporation 1500 Park Road Chanhassen, MN 55317
Device (Trade name):	PMT Platinum Depthalon® Depth Electrodes
Device (Regulation name):	Depth Electrode
Contact:	Kim Schmelzer, Quality Manager PMT Corporation 1500 Park Road Chanhassen, MN 55317 Phone: 952-470-0866 Fax: 952-470-0865 Email: (b)(6)

(b)(5)

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

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INSTRUCTION MANUAL

(b)(4)

Depthalon® Depth Electrode (b)(4)

Depthalon Depth Electrodes (b)(4)

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July 14, 2016</br></br> We have completed our review. Please refer to the attached letter for details.

If you have any questions, please contact the lead reviewer assigned to your submission, Stacie Gutowski.

 *** This is a system-generated email notification ***

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

Records processed under FOIA Request 2024-2207; Released by CDRH on 11-13-2024

From: Williams, Dhanya K
Sent: Friday, July 08, 2016 4:01 PM
To: Gutowski, Stacie
Cc: Williams, Dhanya K
Subject: RE: (b)(5) needed for K151790

Hi Stacie,

(b)(5)

Thanks!
Dhanya

From: Gutowski, Stacie
Sent: Friday, July 08, 2016 3:22 PM
To: Williams, Dhanya K
Subject: FW: (b)(5) needed for K151790

Hi Dhanya,

(b)(5)

(b)(5) Let me know your thoughts.
-Stacie

From: Kim Schmelzer [mailto: (b)(6)
Sent: Friday, July 08, 2016 3:17 PM
To: Gutowski, Stacie
Subject: RE: (b)(4) needed for K151790

Stacie,

(b)(4)

Thank you,
Kim Schmelzer | Quality Manager
PMT Corporation | Permark
1500 Park Road Chanhassen MN 55317 USA
D: +952.470.0866 | F: +952.470.0865
www.pmtcorp.com | www.permark.com

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From: Gutowski, Stacie [mailto:Stacie.Gutowski@fda.hhs.gov]
Sent: Friday, July 08, 2016 2:15 PM
To: Kim Schmelzer

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

Cc: k151790@docs.fda.gov
Subject: RE: (b)(4) needed for K151790

Hi Kim,

(b)(4)

Stacie Gutowski, Ph.D.
Biomedical Engineer
ODE/DNPMD/NSDB
WO 66, Rm 2656
10903 New Hampshire Avenue
Silver Spring, MD 20993
(240) 402-6032
Stacie.Gutowski@fda.hhs.gov

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https://www.research.net/s/cdrhcustomerservice?O=400&D=460&B=462&E=&S=E

From: Kim Schmelzer [mailto:(b)(6)
Sent: Thursday, July 07, 2016 9:54 AM
To: Gutowski, Stacie
Subject: RE: (b)(4) needed for K151790

Stacie,

(b)(4)

Thank you,
Kim Schmelzer | Quality Manager
PMT Corporation | Permark
1500 Park Road Chanhassen MN 55317 USA
D: +952.470.0866 | F: +952.470.0865
www.pmtcorp.com | www.permark.com

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From: Gutowski, Stacie [mailto:Stacie.Gutowski@fda.hhs.gov]
Sent: Thursday, July 07, 2016 6:42 AM
To: Kim Schmelzer
Cc: k151790@docs.fda.gov
Subject: RE: (b)(4) needed for K151790

Hi Kim,

(b)(4)

Stacie Gutowski, Ph.D.
Biomedical Engineer
ODE/DNPMD/NSDB
WO 66, Rm 2656
10903 New Hampshire Avenue
Silver Spring, MD 20993
(240) 402-6032
Stacie.Gutowski@fda.hhs.gov

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From: Kim Schmelzer [mailto:(b)(6)
Sent: Wednesday, July 06, 2016 4:55 PM
To: Gutowski, Stacie
Cc: (b)(6)
Subject: RE: (b)(4) needed for K151790

Stacie,

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(b)(4)

Let me know if you have any further questions on this.

Thank you,
Kim Schmelzer | Quality Manager
PMT Corporation | Permark
1500 Park Road Chanhassen MN 55317 USA
D: +952.470.0866 | F: +952.470.0865
www.pmtcorp.com | www.permark.com

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From: Gutowski, Stacie [mailto:Stacie.Gutowski@fda.hhs.gov]
Sent: Wednesday, July 06, 2016 12:20 PM
To: Kim Schmelzer
Subject: RE: (b)(4) needed for K151790

Hello Kim,

(b)(4)

(b)(4)

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Biomedical Engineer
ODE/DNPMD/NSDB
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From: Kim Schmelzer [mailto: (b)(6)
Sent: Wednesday, July 06, 2016 12:05 PM
To: Gutowski, Stacie
Subject: RE: (b)(4) needed for K151790

Stacie,

(b)(4)

Thank you,
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Sent: Wednesday, July 06, 2016 10:12 AM
To: Kim Schmelzer
Cc: k151790@docs.fda.gov
Subject: [(b)(4)] needed for K151790

Hello Kim,

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ODE/DNPMD/NSDB
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(b)(4) TEST PROTOCOL

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INSTRUCTION MANUAL

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Depthalon® Depth Electrode System

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