

510(k) Summary

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

Dear Ms. Ellis,

(b)(4)

Regards,

Leigh Anderson
Biomedical Engineer
Neurointerventional Devices Team
DHTSA: Division of Neurosurgical, Neurointerventional and Neurodiagnostic Devices
OHTS: Office of Neurological and Physical Medicine Devices
Office of Product Evaluation and Quality
CDRH | Food and Drug Administration
White Oak, Bldg. 66, Rm. 4276 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-5613
leigh.anderson@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?ID=1712&S=E>

THIS MESSAGE IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review, disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify the sender by e-mail or phone.



Food and Drug Administration
CDRH/OPEQ/OHTV/DHTVA
WO66 RM4276
10903 New Hampshire Ave
Silver Spring, MD 20993-0002
301-796-5613

Premarket Notification 510(k) Review

Date: August 4, 2021

Reviewer: Leigh Anderson

Subject: Special 510(k)# K212224

Applicant: Imperative Care Inc.

Contact Name: Kristin Ellis

Correspondent Firm: Imperative Care Inc.

Received Date: July 16, 2021

Pro Code(s): QJP **Class:** II **Reg #:** 870.1250

Pro Code(s): DQY **Class:** II **Reg #:** 870.1250

Device Trade Name: TracStar Large Distal Platform (LDP) Catheter, Zoom 88 Large Distal Platform (LDP) Catheter

Contact Title: Regulatory Affairs Manager

Phone: (408) 857-0934 **Email:** kellis@imperativecare.com

Due Date: August 15, 2021

Reg Name: Percutaneous Catheter

Reg Name: Percutaneous catheter

Predicate Devices:

Submission #	Pro Code	Device Trade Name	Applicant
K203764	QJP,	TracStar Large Distal Platform,	Imperative Care Inc.
	DQY	ZOOM 88 Large Distal Platform,	
		ZOOM 88-T Large Distal Platform	

(b)(5)

(b)(5)

(b)(5)

(b)(5)

(b)(5)

(b)(5)

(b)(5)

(b)(5)

(b)(5)

(b)(5)

(b)(5)

(b)(5)

(b)(5)

(b)(5)

(b)(5)

(b)(5)

(b)(5)

(b)(5)

(b)(5)

(b)(5)

(b)(5)

Dear Ms. Anderson,

(b)(4)

Kind regards,

Kristin Ellis

Regulatory Affairs Manager



M: +1.408.857.0934

E: kellis@imperativecare.com

imperativecare.com | [LinkedIn](#) | [Twitter](#) | [YouTube](#)

1359 Dell Avenue, Campbell, CA 95008

www.imperativecare.com

From: Anderson, Leigh <Leigh.Anderson@fda.hhs.gov>

Sent: Thursday, September 9, 2021 2:11 PM

To: Kristin Ellis <kellis@imperativecare.com>

Cc: K212224@docs.fda.gov

Subject: K212224 - Interactive Request

(b)(4)

Dear Ms. Ellis,

(b)(4)

Regards,

Leigh Anderson

Biomedical Engineer

Neurointerventional Devices Team

DHT5A: Division of Neurosurgical, Neurointerventional and Neurodiagnostic Devices

OHT5: Office of Neurological and Physical Medicine Devices

Office of Product Evaluation and Quality

CDRH | Food and Drug Administration

White Oak, Bldg. 66, Rm. 4276 | 10903 New Hampshire Avenue | Silver Spring, MD 20993

Ph: 301-796-5613

leigh.anderson@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?ID=1712&S=E>

THIS MESSAGE IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review, disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify the sender by e-mail or phone.

FDA/CDRH/DCC

September 1, 2021

SEP 02 2021

RECEIVED

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – W066-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

K212224/S001

Attn: Leigh Anderson, Biomedical Engineer/Premarket Reviewer

RE: Special 510(k) K212224 – Response to FDA Deficiency List Dated August 4, 2021
for the Imperative Care Large Distal Platform Catheters

Dear Ms. Anderson,

Imperative Care Inc. is submitting one electronic copy (eCopy) of this response to the FDA Deficiency List for the Imperative Care Large Distal Platform Catheters Special 510(k) K212224 received on August 4, 2021. The e-copy was prepared in accordance with CDRH's electronic copy program.

The questions and requests from the list have been included on the following pages in bold print, followed by Imperative Care's response.

The existence of this response is confidential, and the protection afforded to such confidential information by 21 CFR 807.95(b), 18 USC 1905, 21 USC 331(j), 5 USC 552, and other applicable laws is hereby claimed.

Your consideration of these responses is very much appreciated. Should you have any additional questions or require further information, please contact me at (408) 857 - 0934 or via email at kellis@imperativecare.com.

In my absence, please do not hesitate to contact Nora Hadding, Senior Vice President, Regulatory Affairs, Quality Assurance, and Clinical Affairs at (763) 458-4999 or via email at nhadding@imperativecare.com.

Sincerely,

(b)(6)

Kristin Ellis - Regulatory Affairs Manager - Imperative Care Inc.

Cc: Nora Hadding - SVP, Regulatory Affairs, Quality Assurance, Clinical Affairs - Imperative Care Inc.

Confidential

Page 1 of 13

Dear Ms. Ellis,

(b)(4)

Regards,

Leigh Anderson
Biomedical Engineer
Neurointerventional Devices Team
DHT5A: Division of Neurosurgical, Neurointerventional and Neurodiagnostic Devices
OHT5: Office of Neurological and Physical Medicine Devices
Office of Product Evaluation and Quality
CDRH | Food and Drug Administration
White Oak, Bldg. 66, Rm. 4276 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-5613
leigh.anderson@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?ID=1712&S=E>

THIS MESSAGE IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review, disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify the sender by e-mail or phone.

Dear Ms. Ellis,

Thank you for reaching out. We have received the response for K212224 and are reviewing the information. If we have any additional questions, we will reach out.

Regards,

Leigh Anderson

Biomedical Engineer

Neurointerventional Devices Team

DHT5A: Division of Neurosurgical, Neurointerventional and Neurodiagnostic Devices

OHT5: Office of Neurological and Physical Medicine Devices

Office of Product Evaluation and Quality

CDRH | Food and Drug Administration

White Oak, Bldg. 66, Rm. 4276 | 10903 New Hampshire Avenue | Silver Spring, MD 20993

Ph: 301-796-5613

leigh.anderson@fda.hhs.gov<mailto:leigh.anderson@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?ID=1712&S=E>

THIS MESSAGE IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review, disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify the sender by e-mail or phone.

From: Kristin Ellis <kellis@imperativecare.com>

Sent: Wednesday, September 8, 2021 12:18 PM

To: Anderson, Leigh <Leigh.Anderson@fda.hhs.gov>

Subject: [EXTERNAL] Response to FDA request for additional information for K212224

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Dear Ms. Anderson,

I hope this email finds you well.

The response to FDA's request for additional information for K212224 was submitted last week. Please let me know if you have any further questions or if I can provide anything else to assist in the review of the Special 510(k).

Kind regards,

Kristin Ellis

Regulatory Affairs Manager

[cid:image001.png@01D7A4AC.AF11F9C0]

M: +1.408.857.0934

E: kellis@imperativecare.com<<mailto:kellis@imperativecare.com>>

[imperativecare.com](http://www.imperativecare.com/)<<http://www.imperativecare.com/>> |
[LinkedIn](https://www.linkedin.com/company/imperativecare/)<<https://www.linkedin.com/company/imperativecare/>> |
[Twitter](https://twitter.com/imperative_care)<https://twitter.com/imperative_care> |
[YouTube](https://www.youtube.com/channel/UCOXtDHTSq28ZgSHkgtwPhyA)<<https://www.youtube.com/channel/UCOXtDHTSq28ZgSHkgtwPhyA>>

1359 Dell Avenue, Campbell, CA 95008

www.imperativecare.com<<http://www.imperativecare.com/>>

Dear Ms. Anderson,

(b)(4)

Kind regards,

Kristin Ellis

Regulatory Affairs Manager

[cid:image001.png@01D7A585.A0C0C3E0]

M: +1.408.857.0934

E: kellis@imperativecare.com<<mailto:kellis@imperativecare.com>>

www.imperativecare.com<<http://www.imperativecare.com/>> |

LinkedIn<<https://www.linkedin.com/company/imperativecare/>> |

Twitter<https://twitter.com/imperative_care> |

YouTube<<https://www.youtube.com/channel/UCOXtDHTSq28ZgSHkgtwPhyA>>

1359 Dell Avenue, Campbell, CA 95008

www.imperativecare.com<<http://www.imperativecare.com/>>

From: Anderson, Leigh <Leigh.Anderson@fda.hhs.gov>

Sent: Thursday, September 9, 2021 2:11 PM

To: Kristin Ellis <kellis@imperativecare.com>

Cc: K212224@docs.fda.gov

Subject: K212224 - Interactive Request -

(b)(4)

(b)(4)

Dear Ms. Ellis,

(b)(4)

leigh.anderson@fda.hhs.gov<mailto:leigh.anderson@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?ID=1712&S=E<https://nam12.safelinks.prototype.outlook.com/?url=https%3A%2F%2Fwww.research.net%2Fs%2Fcdrhcustomerservice%3FID%3D1712%26S%3DE&data=04%7C01%7Ckellis%40imperativecare.com%7C6f34f4d4cbd740eca5f108d973d68b7e%7Cf9bc67a2b9bd4bcc974aec60ef533fdc%7C0%7C0%7C637668187905926085%7CUnknown%7CTWFpbGZsb3d8eyJWlIjoIjMCM4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6IklhaWwiLCJXVCI6Mn0%3D%7C1000&sdata=kgy3WYuF8P8xTlFFKqG1R6uqn5WNj2UFuuYNBuCLVQs%3D&reserved=0>>

THIS MESSAGE IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review, disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify the sender by e-mail or phone.

Dear Ms. Ellis,

Thanks for your email.

You are correct that the Special 510(k) guidance document notes that FDA generally intends to review Special 510(k) submissions within 30 days of receipt. However, we have not been able to complete our review by FDA day 30 for K212224, as the submission is on day 34 of FDA review today.

Just to clarify, the FDA review clock did not reset to 0 after the Additional Information (AINN) response was received, but continued counting from the day of the AINN request (day 19) for K212224. We intend to complete our review within 30 days of receipt of the response, or by October 2, 2021, for K212224 (which would be day 49). It is certainly possible we complete our review sooner than that date, but I cannot confirm a specific date for our review decision. I don't think the potential for the review to take up to an additional 30 days upon receipt of the AINN response is described in any specific document or webpage.

Regards,

Leigh Anderson
Biomedical Engineer
Neurointerventional Devices Team
DHTSA: Division of Neurosurgical, Neurointerventional and Neurodiagnostic Devices
OHTS: Office of Neurological and Physical Medicine Devices
Office of Product Evaluation and Quality
CDRH | Food and Drug Administration
White Oak, Bldg. 66, Rm. 4276 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-5613
leigh.anderson@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?ID=1712&S=E>

THIS MESSAGE IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review, disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify the sender by e-mail or phone.

From: Kristin Ellis <kellis@imperativecare.com>
Sent: Friday, September 17, 2021 10:51 AM
To: Anderson, Leigh <Leigh.Anderson@fda.hhs.gov>
Cc: Nora Hadding <nhadding@imperativecare.com>; K212224@docs.fda.gov
Subject: RE: [EXTERNAL] K212224 Review Status

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Good morning Ms. Anderson,

I know you must be very busy but I'm hoping that you can help me to better understand the review process for Special 510(k)s and the impact to the review time with issuance of an Additional Information letter. I reviewed the FDA Guidance Document "FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Goals, Guidance for Industry and Food and Drug Administration Staff" issued on October 2, 2017 and was not able to locate any language which indicates a reset of the review clock to 30 days for Special 510(k)s. The guidance document indicates that the clock stops upon issuance of a request for additional information and starts again upon receipt of the information. Following this guidance, I was under the impression that the review clock would have started back up at day 20 when Document Control received the requested additional information. Any help you can provide in indicating where I missed this information is appreciated for future submissions so that I can correctly advise project teams.

In addition, is it possible that we will be receiving a response sooner than Oct.2? As always, please let me know if there is any additional information we can provide for the review.

I appreciate the time you have already spent reviewing K212224 and answering my earlier questions. Thank you in advance for taking the time to address these additional questions for my understanding.

Kind regards,
Kristin Ellis

Kristin Ellis
Regulatory Affairs Manager



M: +1.408.857.0934
E: kellis@imperativecare.com
imperativecare.com | [LinkedIn](#) | [Twitter](#) | [YouTube](#)

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

1359 Dell Avenue, Campbell, CA 95008
www.imperativecare.com

From: Anderson, Leigh <Leigh.Anderson@fda.hhs.gov>
Sent: Tuesday, September 14, 2021 1:49 PM
To: Kristin Ellis <kellis@imperativecare.com>
Cc: Nora Hadding <nhadding@imperativecare.com>; K212224@docs.fda.gov
Subject: RE: [EXTERNAL] K212224 Review Status

Dear Ms. Ellis,

Our goal is to complete review of the response within 30 days of receipt, which shows to be October 2, 2021, in our document tracking system.

Regards,

Leigh Anderson
Biomedical Engineer
Neurointerventional Devices Team
DHTSA: Division of Neurosurgical, Neurointerventional and Neurodiagnostic Devices
OHTS: Office of Neurological and Physical Medicine Devices
Office of Product Evaluation and Quality
CDRH | Food and Drug Administration
White Oak, Bldg. 66, Rm. 4276 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-5613
leigh.anderson@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?ID=1712&S=E>

THIS MESSAGE IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review, disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify the sender by e-mail or phone.

From: Kristin Ellis <kellis@imperativecare.com>
Sent: Tuesday, September 14, 2021 12:45 PM
To: Anderson, Leigh <Leigh.Anderson@fda.hhs.gov>
Cc: Nora Hadding <nhadding@imperativecare.com>; K212224@docs.fda.gov
Subject: RE: [EXTERNAL] K212224 Review Status

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Dear Ms. Anderson,

Thank you for the correction of the review clock day. Can you please provide me with the submission timing review goal for this Special 510(k)? This would be helpful for our planning purposes.

Kind regards,

Kristin Ellis
Regulatory Affairs Manager



M: +1.408.857.0934
E: kellis@imperativecare.com
imperativecare.com | LinkedIn | Twitter | YouTube

1359 Dell Avenue, Campbell, CA 95008
www.imperativecare.com

From: Anderson, Leigh <Leigh.Anderson@fda.hhs.gov>
Sent: Tuesday, September 14, 2021 9:22 AM
To: Kristin Ellis <kellis@imperativecare.com>
Cc: Nora Hadding <nhadding@imperativecare.com>; K212224@docs.fda.gov
Subject: RE: [EXTERNAL] K212224 Review Status

Dear Ms. Ellis,

Thank you for your email.

Our review tracking system indicates that today is day 31 of FDA's review clock for K212224. The submission is still under review at this time. If we have additional questions, we will reach out as soon as possible.

Regards,

Leigh Anderson
Biomedical Engineer
Neurointerventional Devices Team
DHT5A: Division of Neurosurgical, Neurointerventional and Neurodiagnostic Devices
OHT5: Office of Neurological and Physical Medicine Devices
Office of Product Evaluation and Quality
CDRH | Food and Drug Administration
White Oak, Bldg. 66, Rm. 4276 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-5613
leigh.anderson@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?ID=1712&S=E>

THIS MESSAGE IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review, disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify the sender by e-mail or phone.

From: Kristin Ellis <kellis@imperativecare.com>
Sent: Tuesday, September 14, 2021 11:48 AM
To: Anderson, Leigh <Leigh.Anderson@fda.hhs.gov>
Cc: Nora Hadding <nhadding@imperativecare.com>
Subject: [EXTERNAL] K212224 Review Status

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Good morning Ms. Anderson,

I hope this email finds you well. I am contacting you with regards to the review status of K212224. With the request for additional information hold and the Labor Day holiday, I am unsure of the review clock day count. I believe the clock is currently at Day 32. Can you please confirm if this is correct or if not, what date is the end of the review cycle?

Additionally, please let me know if there is any further information you require to complete the review.

Kind regards,

Kristin Ellis
Regulatory Affairs Manager



M: +1.408.857.0934
E: kellis@imperativecare.com
imperativecare.com | [LinkedIn](#) | [Twitter](#) | [YouTube](#)

1359 Deli Avenue, Campbell, CA 95008
www.imperativecare.com

PREMARKET NOTIFICATION**TRUTHFUL AND ACCURATE STATEMENT****[As Required by 21 CFR 807.87(l)]**

I certify that, in my capacity as Regulatory Affairs Manager for Imperative Care Inc., I believe to the best of my knowledge, that all data and information submitted in the pre-market notification are truthful and accurate and that no material facts have been omitted.

(b)(6)

Kristin Ellis

Regulatory Affairs Manager

Tel: (408) 857-0934

E-mail: kellis@imperativecare.com07/15/2021

Date

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

510(k) Summary

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

Dear Ms. Ellis,

Thank you for confirming receipt and for working with us interactively to address questions during review.

Regards,

Leigh Anderson
Biomedical Engineer
Neurointerventional Devices Team
DHT5A: Division of Neurosurgical, Neurointerventional and Neurodiagnostic Devices
OHT5: Office of Neurological and Physical Medicine Devices
Office of Product Evaluation and Quality
CDRH | Food and Drug Administration
White Oak, Bldg. 66, Rm. 4276 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-5613
leigh.anderson@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?ID=1712&S=E>

THIS MESSAGE IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review, disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify the sender by e-mail or phone.

From: Kristin Ellis <kellis@imperativecare.com>
Sent: Monday, September 20, 2021 2:05 PM
To: Anderson, Leigh <Leigh.Anderson@fda.hhs.gov>
Subject: [EXTERNAL] RE: K212224/S001 Review Complete

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Dear Ms. Anderson,

Thank you for the completion of the review. I appreciate your efforts and the answers to all of my questions.

Kind regards,

.....
Kristin Ellis
Regulatory Affairs Manager



M: +1.408.857.0934
E: kellis@imperativecare.com
imperativecare.com | [LinkedIn](#) | [Twitter](#) | [YouTube](#)

1359 Dell Avenue, Campbell, CA 95008
www.imperativecare.com

From: Leigh Anderson [LEIGH.ANDERSON] <leigh.anderson@fda.hhs.gov>
Sent: Monday, September 20, 2021 11:00 AM
To: Kristin Ellis <kellis@imperativecare.com>
Cc: Leigh Anderson [LEIGH.ANDERSON] <leigh.anderson@fda.hhs.gov>
Subject: K212224/S001 Review Complete

September 20, 2021

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, Leigh Anderson.

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

Dear Ms. Ellis,

I am lead reviewer for K212224 for the TracStar and Zoom 88 Large Distal Platform Catheters. We are still early in our review and primarily in the administrative RTA review phase.

(b)(4)

(b)(4)

We request that you provide a response to the following items via email by Monday, July 26 to facilitate our review. If you have concerns with the proposed timeline, please let me know.

FDA Request:

(b)(4)

Regards,

Leigh Anderson

Biomedical Engineer

Neurointerventional Devices Team

DHT5A: Division of Neurosurgical, Neurointerventional and Neurodiagnostic Devices

OHT5: Office of Neurological and Physical Medicine Devices

Office of Product Evaluation and Quality

CDRH | Food and Drug Administration

White Oak, Bldg. 66, Rm. 4276 | 10903 New Hampshire Avenue | Silver Spring, MD 20993

Ph: 301-796-5613

leigh.anderson@fda.hhs.gov<mailto:leigh.anderson@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?ID=1712&S=E>

THIS MESSAGE IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review, disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify the sender by e-mail or phone.



U.S. FOOD & DRUG
ADMINISTRATION

[Build Correspondence](#)

[Convert to PDF](#)

September 20, 2021

Imperative Care, Inc.
Kristin Ellis
Regulatory Affairs Manager
1359 Dell Avenue
Campbell, California 95008

Re: K212224

Trade/Device Name: TracStar LDP Large Distal Platform; Zoom 88 Large Distal Platform
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: QJP, DQY
Dated: September 1, 2021
Received: September 2, 2021

Dear Kristin Ellis:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm> identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part

801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see <https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products>); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance>) and CDRH Learn (<https://www.fda.gov/training-and-continuing-education/cdrh-learn>). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice>) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Naira Muradyan, Ph.D.
Assistant Director
DHT5A: Division of Neurosurgical,
Neurointerventional
and Neurodiagnostic Devices
OHT5: Office of Neurological
and Physical Medicine Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

September 20, 2021</br></br><p>We have completed our review. Please refer to the attached letter for details.</p>

<p>If you have any questions, please contact the lead reviewer assigned to your submission, Leigh Anderson.</p>

<p>*** This is a system-generated email notification ***</p>

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: https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/ucm370879.htm	
1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code) Imperative Care, Inc. 1359 Dell Ave Campbell California CA 95008 US 1.1 EMPLOYER IDENTIFICATION NUMBER (EIN) *****6960	2. CONTACT NAME Kristin Ellis 2.1 E-MAIL ADDRESS kellis@imperativecare.com 2.2 TELEPHONE NUMBER (include Area code) (b)(6) 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) <u>Select an application type:</u> ☒ 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 ☐ De Novo Request 3.1 Select a center ☒ CDRH ☐ CBER 3.2 Select one of the types below ☒ Original Application <u>Supplement Types:</u> ☐ 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 NO, I am not a small business 4.1 If Yes, please enter your Small Business Decision Number: SBD217180	
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? ☒ YES (All of your establishments have registered and paid the fee, or this is your first device and you will register and pay the fee within 30 days after entering into an operation that requires you to register and submit device listing information.) ☐ NO (If you currently market a medical device and your establishment is required to register and submit device listing information, FDA will not accept your submission until you have paid all fees due to FDA. See http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/RegistrationandListing/ucm053165.htm for additional information)	
6. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION. ☐ This application is the first PMA submitted by a qualified small business, including any affiliates ☐ This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only ☐ The sole purpose of the application is to support conditions of use for a pediatric population ☐ 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 ☒ 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, Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118	

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
Paper Reduction Act (PRA) Staff
PRASStaff@fda.hhs.gov

[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)

30-Jun-2021

Form FDA 3601 (08/19)

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

August 4, 2021</br></br><p>We have reviewed your submission. Please see attached. </p>

<p>If you have any questions, please contact the lead reviewer assigned to your submission, Leigh Anderson. </p>

<p>*** This is a system-generated email notification ***</p>

510(k) Summary

A. Submitter Information

Submitter's Name: Imperative Care, Inc.
Address: 1359 Dell Avenue
Campbell, CA 95008
Contact Person: Kristin Ellis
Telephone: 408-857-0934
Email: kellis@imperativecare.com
Date of Preparation: September 1, 2021

B. Subject Device

Proprietary Names: TracStar™ LDP Large Distal Platform
Zoom™ 88 Large Distal Platform
Common/Usual Name: Guide Catheter
Classification Name: Catheter, Percutaneous, Neurovasculature
Product Code: QJP
DQY
Regulation: 21 CFR 870.1250

C. Predicate Device(s)

Proprietary Name: TracStar™ Large Distal Platform
Zoom™ 88 Large Distal Platform
Zoom™ 88-T Large Distal Platform
Common/Usual Name: Guide Catheter
Classification Name: Catheter, Percutaneous
Product Code: QJP, DQY
Regulation: 21 CFR. 870.1250
Manufacturer: Imperative Care Inc.
510(k): K203764

Proprietary Name: EagleRay Long Sheath
EagleRay Access Catheter
Common/Usual Name: Guide Catheter
Classification Name: Catheter, Percutaneous
Product Code: DQY
Regulation: 21 CFR. 870.1250
Manufacturer: Imperative Care Inc.
510(k): K180169

D. Device Description:

The Imperative Care Large Distal Platform (LDP) Catheters include the TracStar™ LDP Large Distal Platform and Zoom™ 88 Large Distal Platform. The LDP Catheters are 0.038" diameter or smaller guidewire compatible single lumen guide catheters that provide

access to peripheral, coronary and neuro vasculature. The catheters are comprised of a hollow cylindrical tube bonded at the proximal end to a standard luer fitting. The wall of the tube is constructed using a combination of metal coils/braids and medical grade polymers. The distal section of each catheter has a hydrophilic coating to enhance tracking through tortuous vasculature. An angled distal soft tip facilitates smooth tracking past vessel branches. A radiopaque marker provides visual confirmation of the distal tip location under fluoroscopy. LDP Catheters have an inner diameter of 0.088" (6F compatible), and a maximum outer diameter of 0.110". The LDP guide catheters are packaged with a rotating hemostasis valve (RHV) that is attached to the proximal luer to help maintain hemostasis.

Accessory devices required, but not supplied include:

- Guidewires
- Support/diagnostic catheters
- Introducer sheaths

E. Indications for Use:

The TracStar LDP Large Distal Platform is indicated for the introduction of interventional devices into the peripheral, coronary, and neuro vasculature.

The Zoom 88 Large Distal Platform is indicated for the introduction of interventional devices into the peripheral, coronary, and neuro vasculature.

F. Principles of Operation:

The LDP Catheters may be used with support catheters to assist in accessing the target vasculature. During use, the male luer of the RHV is attached to the proximal luer of the LDP Catheter to create a continuous lumen through the catheter and to the RHV ports. The female luer is typically connected to a saline drip line while the LDP Catheter is advanced through the vasculature. Use of the LDP Catheter relies on standard percutaneous interventional techniques, including access site preparation, introducing the catheter portion of the device, advancing the catheter under fluoroscopy, withdrawing the catheter, and closing the access site.

G. Predicate Comparison:

The predicate devices are the Imperative Care LDP Catheters cleared under K203764 and K180169. The predicate and subject devices share the same intended use, basic technological characteristics, and the same performance characteristics, demonstrated through bench and

laboratory testing as shown in **Table 1**. Modifications to the predicate include dimensional updates, additional axial and radial reinforcements, and manufacturing process improvements.

Table 1: Comparison of Subject and Predicate Device

Device Attribute	Subject device	Predicate device(s)	
FDA Product Classification	Class II, QJP and DQY, 21 CFR 870.1250	Class II, QJP and DQY, 21 CFR 870.1250	Class II, DQY, 21 CFR 870.1250
Product Name	TracStar LDP Large Distal Platform Zoom 88 Large Distal Platform	TracStar Large Distal Platform Zoom 88 Large Distal Platform Zoom 88-T Large Distal Platform	EagleRay Long Sheath EagleRay Access Catheter
510(k) Number	K212224	K203764	K180169
Indications for Use	The TracStar LDP Large Distal Platform is indicated for the introduction of interventional devices into the peripheral, coronary, and neuro vasculature. The Zoom 88 Large Distal Platform is indicated for the introduction of interventional devices into the peripheral, coronary, and neuro vasculature.	The TracStar Large Distal Platform is indicated for the introduction of interventional devices into the peripheral, coronary, and neuro vasculature. The Zoom 88 and Zoom 88-T Large Distal Platform are indicated for the introduction of interventional devices into the peripheral, coronary, and neuro vasculature.	The EagleRay Long Sheath and EagleRay Access Catheter are indicated for the introduction of interventional devices into the peripheral, coronary, and neuro vasculature.
Condition Supplied	Sterile and Single Use	Same	Same
Sterilization Method	Ethylene Oxide (EtO), SAL 10^{-6}	Same	Same
Inner Diameter (Distal)	0.088"	Same	Same
Outer Diameter (Distal)	0.106"	Same	Same
Inner Diameter (Proximal)	0.088"	Same	Same
Outer Diameter (Proximal)	0.110"	Same	Same

Device Attribute	Subject device	Predicate device(s)	
Effective Length	80 - 110cm	Same	Same
Tip Design	Beveled distal edge, soft, flexible, atraumatic tip	Same	Same
Distal Catheter Shaft	Additional polymer reinforcement	Reinforced with metals and polymers	Reinforced with metals and polymers
Proximal Catheter Shaft	Additional radial reinforcement	Reinforced with metals and polymers	Reinforced with metals and polymers
Coating	Hydrophilic coating	Same	Same
Materials	Commonly used medical grade plastics & metals with hydrophilic coating	Same	Same
Packaged Accessories	Rotating Hemostasis Valve (RHV)	Same	Same
Packaging Configuration	The catheters are placed in a protective polyethylene tube, mounted with accessory RHV onto a polyethylene packaging card, placed into a pouch, sealed and labeled. The sealed pouch and IFU are placed in a labeled shelf carton box.	Same	Same

H. Performance Data Supporting Substantial Equivalence:

Bench and Laboratory (in-vitro) test was completed to evaluate the differences between the subject LDP Catheters and predicate LDP Catheters. Performance specifications and test methods were based primarily on catheter performance standard ISO 10555-1 and a summary of the evaluated performance specifications is presented in **Table 2**.

The test results were reviewed and found to demonstrate that the differences between the subject LDP Catheters and predicate LDP Catheters do not significantly impact any performance parameters that would negatively affect the safety or effectiveness of the subject LDP Catheters.

Table 2: Tests and Performance Specifications

Test Attribute	Specification	Results
Delivery, Compatibility, and Retraction (Trackability)	The catheter shall be able to be delivered, deployed, and retracted per the IFU within a simulated neurological model without incurring any damage to the catheter.	Pass
Flexibility and Kink Resistance	There shall be no kinking of shaft (permanent deformation) after simulated use.	Pass
Compatibility with other Devices (external)	The catheters shall be able to be delivered through the minimum introducer sheath or guide catheter size indicated in the product labeling.	Pass
Guidewire Compatibility	The catheters shall be able to be delivered over the maximum size guidewire indicated in the product labeling.	Pass
Interventional Device Compatibility (internal)	The catheters shall be able to accommodate other interventional devices (e.g., support catheter, diagnostic catheter) up to the maximum size indicated in the product labeling.	Pass
Luer Compatibility	Devices and accessories shall be compatible with standard syringe luer fittings per ISO 80369-7.	Pass
Accessory Compatibility	Devices shall be compatible with an RHV.	Pass
Catheter Bond Strength	The catheter shall have sufficient bond strengths to remain intact throughout a procedure.	Pass
Freedom from Leakage – positive pressure	No liquid leakage from the hub or catheter shaft at 46psi for 30 seconds	Pass
Freedom from Leakage – negative pressure	No air leakage into a 20cc syringe when vacuum pulled for 15 seconds.	Pass
Dynamic Burst Pressure	Catheter does not burst under pressures that could be seen when performing contrast injections with a standard 10cc syringe.	Pass
Static Burst Pressure	Catheter does not burst under pressures that could be seen when performing contrast injections with a standard 10cc syringe.	Pass

Test Attribute	Specification	Results
Catheter Torque Strength	With the catheter tip held in a static position, there shall be no separation of any portion of the catheter when rotated at the hub at least two (2) full rotations (720 degrees).	Pass
Kink Resistance	There shall be no kinking of the catheter shaft (permanent deformation) after wrapping around anatomically relevant bend radii.	Pass
Pushability	The proximal shaft of the catheters shall have sufficient stiffness that the user can easily push the catheter to the target anatomy without buckling.	Pass
Access Force	Catheters shall not require excessive force to safely navigate and track to the target anatomy.	Pass

I. Biocompatibility Testing:

There are no changes to patient contacting materials compared to the predicate device. Therefore, the original testing on the predicate devices applies to the subject devices and additional biocompatibility testing was not required.

J. Sterilization:

The LDP Catheters are sterilized using a validated EtO process with a sterility assurance level of 1×10^{-6} validated per the overkill method in accordance with ISO 11135, "Sterilization Of Health-Care Products - Ethylene Oxide - Requirements For The Development, Validation And Routine Control Of A Sterilization Process For Medical Devices".

K. Shelf Life and Packaging:

Accelerated aging testing based on ASTM F1980 was conducted to verify packaged device performance. A real time aging equivalent of 13 months was used to support a 1-year shelf life claim. Device performance was verified by functional and performance testing.

There are no changes to packaging compared to the predicate device. Therefore, the original testing on the predicate devices applies to the subject devices and additional packaging validation testing was not required.

L. Conclusions:

Where differences were identified between the subject and predicate devices, a risk assessment was completed to determine if the difference would result in new safety or effectiveness concerns. As appropriate, previous bench and laboratory testing was evaluated for applicability and either the rationale for no impact was documented or verification and validation was repeated as required.

Based on the results of the risk assessments and associated bench and laboratory testing, the subject and predicate devices are substantially equivalent and there are no new safety or effectiveness concerns. The subject device and predicate device share the same intended use, basic technological characteristics, and performance characteristics.

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

Date of Submission 07/15/2021	User Fee Payment ID Number (b)(4)	FDA Submission Document Number (if known)
----------------------------------	--------------------------------------	---

SECTION A TYPE OF SUBMISSION

PMA & PDP ☐ Original ☐ Modular Submission ☐ Amendment ☐ Report (annual or PAS) ☐ Report Amendment ☐ Other: ☐ Premarket Report (reprocessed SUD) ☐ Licensing Agreement	PMA/PDP Supplement ☐ 180 day - PAS protocol or labeling change, location change, trade name change ☐ 180 day - Design or labeling change ☐ Special CBE ☐ Panel Track ☐ 30-day Notice ☐ Real-time Review ☐ Amendment to PMA/PDP Supplement	510(k) ☒ Original Submission: ☐ Traditional ☒ Special ☐ Abbreviated ☐ 3rd Party Traditional ☐ 3rd Party Special ☐ 3rd Party Abbreviated ☐ Dual Track (Dual 510(k) and CLIA Waiver by Application) ☐ Amendment ☐ Supplement	CLIA CLIA Categorization Record (CR) ☐ Original ☐ Amendment CLIA Waiver by Application (CW) ☐ Original ☐ Amendment ☐ Supplement	Q-Submission ☐ Pre-Submission ☐ Informational Meeting ☐ Submission Issue Meeting ☐ Day 100 Meeting ☐ Agreement Meeting ☐ Determination Meeting ☐ Study Risk Determination ☐ Other (Specify below)
IDE ☐ Original IDE: ☐ Amendment to Original IDE ☐ Supplement: ☐ Amendment to Supplement ☐ Report: ☐ Amendment to Report	HDE ☐ Original Submission ☐ Amendment to Original ☐ Report ☐ Report Amendment ☐ HDE Supplement: ☐ 75-day Supplement ☐ 30-day Notice ☐ Special CBE ☐ Amendment to Supplement	Class II Exemption Petition ☐ Original Submission ☐ Additional Information Emergency Use Authorization ☐ Original ☐ Supplement ☐ Amendment ☐ Report	De Novo ☐ Original: ☐ Direct ☐ Post-NSE ☐ Amendment ☐ Supplement Pre-Emergency Use Authorization ☐ Original ☐ Supplement ☐ Amendment	Other Submission ☐ 513(g) ☐ Appeal ☐ Other (Briefly describe submission below)

Expanded Access to Devices

- ☐ Compassionate Use Request **NOT associated with an IDE**
☐ Follow-up Report for Compassionate Use **NOT associated with an IDE**
☐ Emergency Use Follow-up Report **NOT associated with an IDE**

SECTION B APPLICANT / SPONSOR

Company/Institution Name Imperative Care Inc.		Establishment Registration Number/FEI (if known) 3014590708	
Street Address 1359 Dell Avenue		City Campbell	
State/Province CA	ZIP/Postal Code 95008	Country USA	
Contact Name Kristin Ellis		Contact Title Regulatory Affairs Manager	
Division Name (if applicable) N/A		Phone Number (including area code) (408) 857-0934	
Fax Number (including area code) N/A		Contact Email Address KEllis@imperativecare.com	

SECTION C OFFICIAL CORRESPONDENT (e.g., may be a consultant and/or 510(k) Third Party) (if different from Section B)

Company/Institution Name		Establishment Registration Number/FEI (if known)	
Street Address		City	
State/Province	ZIP/Postal Code	Country	
Contact 1 Name		Contact 1 Title	
Contact 1 Division Name (if applicable)		Contact 1 Phone Number (including area code)	
Contact 1 Fax Number (including area code)	Contact 1 Email Address		
Contact 2 Name		Contact 2 Title	
Contact 2 Division Name (if applicable)		Contact 2 Phone Number (including area code)	
Contact 2 Fax Number (including area code)	Contact 2 Email Address		
Contact 3 Name		Contact 3 Title	
Contact 3 Division Name (if applicable)		Contact 3 Phone Number (including area code)	
Contact 3 Fax Number (including area code)	Contact 3 Email Address		

To add another set of Section C items, please click on the button to the right. May be repeated as needed.

Add Section C

SECTION D INTENDED USE POPULATION

Check all that apply.

- | | | |
|--|---|--|
| ☒ Adults Only (greater than 21 years of age) | ☐ Neonate/Newborn (birth through 28 days) | ☐ Other (Specify below) |
| ☐ Adults and Pediatrics | ☐ Infant (from 29 days to 2 years of age) | |
| | ☐ Child (from 2 years to 12 years of age) | |
| | ☐ Adolescent (from 12 years to 18 years of age) | |
| | ☐ Transitional Adolescent A (18 through 21 years of age) | |
| | ☐ Transitional Adolescent B (18 through 21 years of age) | |

SECTION E PRODUCT INFORMATION – APPLICABLE TO ALL SUBMISSIONS

Trade Name

1 TracStar Large Distal Platform (LDP) Catheter

2 Zoom 88 Large Distal Platform (LDP) Catheter

3

4

5

Common/Generic Name (Include if no Trade Name)

SECTION F PRIOR RELATED SUBMISSIONS FOR THIS DEVICE OR STUDYFDA document numbers of all prior related submissions (*regardless of outcome*) or state no prior submission in box 1.

1 K180169

2 K203764

3

4

5

6

7

8

9

10

11

12

SECTION G PRODUCT CLASSIFICATION – APPLICABLE TO ALL SUBMISSIONSProduct Code(s) (*when applicable*) (*If more than one, please separate with commas.*)

DQY, QJP

C.F.R. Section (*If applicable*)

21 C.F.R 870.1250

Classification Panel/Medical Specialty

Neurology

Device Class

☐ Class I☒ Class II☐ Class III☐ Unclassified**SECTION H1 REASON FOR APPLICATION – PMA, PDP, OR HDE**

- ☐ New Device
☐ STED

☐ Post-approval Study Protocol☐ HDE Request for Annual Distribution Number (ADN)☐ Change in Design, Component, or Specification:

- ☐ Software/Hardware
☐ Color Additive
☐ Material
☐ Specifications
☐ Other (*Specify below*)

☐ Location Change:

- ☐ Manufacturer
☐ Sterilizer
☐ Packager

☐ Report Submission:

- ☐ Annual or Periodic
☐ Post-approval Study

☐ Process Change:

- ☐ Manufacturing
☐ Packaging
☐ Sterilization
☐ Vendor/Supplier Change
☐ Other (*Specify below*)

☐ Labeling Change:

- ☐ Indications
☐ Instructions
☐ PAS update
☐ Performance Characteristics
☐ Shelf Life
☐ Trade Name
☐ Other (*Specify below*)

☐ Amendment:

- ☐ Withdrawal
☐ Change in Ownership
☐ Change in Correspondent
☐ Change of Address
☐ Request for Extension
☐ Response to FDA Correspondence
☐ Other (*Specify below*)

☐ Bundle Submission – *If this is selected, list in the spaces below any PMAs in the Bundle.*

1

2

3

4

5

6

7

8

9

SECTION H2**REASON FOR APPLICATION – IDE**

☐ Original IDE		☐ Report: ☐ Adverse Effect ☐ Final, Study Completed ☐ Annual Progress ☐ Interim Progress ☐ Semiannual Investigator List ☐ Failure to Obtain Informed Consent ☐ Compassionate Use Follow-up ☐ Emergency Use ☐ Live Case Follow-up ☐ Completion of Patient Enrollment ☐ Completion of Patient Follow-up ☐ Other (Specify below)
☐ Supplement: ☐ New Study/New Protocol ☐ Change in Correspondent ☐ Change in Manufacturer ☐ Change in Sponsor ☐ Change in Design ☐ Change in Informed Consent ☐ Change in Manufacturing ☐ Change in Protocol ☐ 5-Day Notice – Device or Manufacturing ☐ 5-Day Notice – Protocol ☐ Compassionate Use Request (under an IDE) ☐ Live Case Request ☐ Request Deviation from Protocol ☐ Expansion of Study (Study/Sites) ☐ Extension of Time to Submit Annual Report or Respond to FDA Letter		
☐ Supplement (Continued) ☐ Request for Waiver ☐ IRB Certification ☐ Request for CMS Recategorization ☐ Study Resumed ☐ Study Suspension ☐ Other (Specify below)		
☐ Amendment to Original IDE: ☐ Amendment Before Final Decision ☐ Response to Refuse to Accept ☐ Response to Disapproval ☐ Response to Approval with Conditions ☐ Withdrawal ☐ Other (Specify below)	☐ Amendment to Supplement: ☐ Response to Disapproval ☐ Response to Approval with Conditions ☐ Withdrawal ☐ Amendment Before Final Decision (additional Information) ☐ Other (Specify below)	☐ Amendment to Report: ☐ Response to Deficiency Letter ☐ Withdrawal ☐ Amendment Before Final Decision (additional Information) ☐ Other (Specify below)

SECTION H3**REASON FOR SUBMISSION – Q-SUBMISSION**

☐ Pre-Submission: ☐ Request Face-to-Face Meeting ☐ Request Teleconference ☐ Request Email Response ☐ Submit Meeting Minutes ☐ Request Meeting Minutes Disagreement T-con	☐ Submission Issue Meeting: ☐ Request Face-to-Face Meeting ☐ Request Teleconference ☐ Request Email Response ☐ Submit Meeting Minutes ☐ Request Meeting Minutes Disagreement T-con	☐ Additional Information ☐ Change in Legal Entity: ☐ Change in Correspondent ☐ Change in Sponsors ☐ Change in Manufacturer ☐ Other (Specify below)
☐ Agreement Meeting: ☐ Request Face-to-Face Meeting ☐ Request Teleconference	☐ Determination Meeting: ☐ Request Face-to-Face Meeting ☐ Request Teleconference	☐ Informational Meeting: ☐ Request Face-to-Face Meeting ☐ Request Teleconference ☐ Submit Meeting Minutes ☐ Request Meeting Minutes Disagreement T-Con
☐ Other (Specify):		

SECTION H4**REASON FOR SUBMISSION – 510(k)**

- ☒ Original
☐ Withdrawal of Original

- ☐ Amendment Before Final Decision:
☐ Change in Ownership
☐ Change in Correspondent
☐ Withdrawal

- ☐ Supplement:
☐ Response to Refuse to Accept (RTA)
☐ Response to Additional Information Request
☐ Withdrawal

- ☐ Amendment After Final Decision

- ☐ Reprocessed SUD

- ☐ Corrective Action

- ☐ STED

- ☐ Third Party (Complete Section C)

- ☐ Other Reason (Specify):

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

	510(k) Number	Trade Name	Submitter	Product Code
Primary Predicate (A)	K203764	Imperative Care LDP Catheters	Imperative Care Inc.	DQY, QJP
Predicate or Reference Device (B)	K180169	EagleRay Long Sheath	Imperative Care Inc.	DQY

To add another Predicate or Reference Device (B) entry row, please click on the button to the right. May be repeated as needed.

Add Device
Information

SECTION H5**DE NOVO SUBMISSIONS**

- ☐ Post NSE De Novo: Number of the 510(k) that was NSE'd in the past 30 days:
☐ Withdrawal

SECTION H6**REASON FOR APPLICATION – CLIA**

Includes CLIA Parent Document number, CR number, or CW number.

- ☐ **CLIA Categorization Record (CR):**
☐ CLIA Categorization of marketed device (include marketing submission number)
☐ CLIA Categorization of device exempt from premarket review
☐ Additional information regarding an open CR (include CR number)

- ☐ **CLIA Waiver by Application (CW):**
☐ Request for CLIA Waiver by Application for marketed device (include marketing submission number)
☐ Request for Dual 510(k) Clearance and CLIA Waiver by Application (include Pre-submission number)
☐ Response to FDA correspondence
☐ Additional information regarding an open CW (include CW number)

- ☐ **Other Reason (Specify)**

SECTION I MANUFACTURING / PACKAGING / STERILIZATION SITES RELATING TO A SUBMISSION**Applicable only to IDEs**

Note: Submission of this information does not affect Registration and Listing.

FDA Document Number (if known)

☐ Original
☐ Add ☐ Delete

Facility Establishment Identifier (FEI) Number

☐ Manufacturer ☐ Contract Sterilizer
☐ Contract Manufacturer ☐ Repackager/Relabeler

Company/Institution Name

Establishment Registration Number/FEI (if known)

Street Address

City

State/Province

ZIP/Postal Code

Country

Contact 1 Name

Contact 1 Title

Contact 1 Division Name (if applicable)

Contact 1 Phone Number (including area code)

Contact 1 Fax Number (including area code)

Contact 1 Email Address

Contact 2 Name

Contact 2 Title

Contact 2 Division Name (if applicable)

Contact 2 Phone Number (including area code)

Contact 2 Fax Number (including area code)

Contact 2 Email Address

Contact 3 Name

Contact 3 Title

Contact 3 Division Name (if applicable)

Contact 3 Phone Number (including area code)

Contact 3 Fax Number (including area code)

Contact 3 Email Address

☐ Original
☐ Add ☐ Delete

Facility Establishment Identifier (FEI) Number

☐ Manufacturer ☐ Contract Sterilizer
☐ Contract Manufacturer ☐ Repackager/Relabeler

Company/Institution Name

Establishment Registration Number/FEI (if known)

Street Address

City

State/Province

ZIP/Postal Code

Country

Contact 1 Name

Contact 1 Title

Contact 1 Division Name (if applicable)

Contact 1 Phone Number (including area code)

Contact 1 Fax Number (including area code)

Contact 1 Email Address

Contact 2 Name	Contact 2 Title
Contact 2 Division Name (if applicable)	Contact 2 Phone Number (including area code)
Contact 2 Fax Number (including area code)	Contact 2 Email Address
Contact 3 Name	Contact 3 Title
Contact 3 Division Name (if applicable)	Contact 3 Phone Number (including area code)
Contact 3 Fax Number (including area code)	Contact 3 Email Address

To add another set of Section I items, please click on the button to the right. May be repeated as needed.

Add Section I

SECTION J**UTILIZATION OF STANDARDS**

Note: Please see guidance document titled "Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices" for details on the Declaration of Conformity.

How to fill out this section:

Recognition Number: State the FDA recognition number. If the standard is not recognized, write **NR**.

Declaration of Conformity or General Use: Select 'Declaration of Conformity' if including a "Declaration of Conformity to a Recognized Standard" statement. For all other uses, select 'General Use' and indicate if you have made deviations from the Recognized/Non-recognized standard.

Standard: State the Standards Development Organization (SDO), the Designation Number (including year), and the Title.

Location: State the section and/or the page number(s) in the submission where the standard is applied.

Examples

Recognition Number	Declaration of Conformity or General Use	Standards Development Organization (SDO), Designation Number-Year, and Title	Location
--------------------	--	--	----------

(b)(4)

Entries for Utilization of Standards

Recognition Number	Declaration of Conformity or General Use	Standards Development Organization (SDO), Designation Number-Year, and Title	Location
--------------------	--	--	----------

(b)(4)

2 ☒	14-529	General Use	If General Use, Deviation? Yes	ISO11135-2014 Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for	(b)(4)
--	--------	-------------	-----------------------------------	--	--------

(b)(4)

(b)(4)

11 ☒	6-408	General Use	If General Use, Deviation? Yes	ISO 10555-1-2014, Intravascular catheters - Sterile and single-use intravascular catheters - Part 1: General requirements	(b)(4)
12 ☒	5-115	General Use	If General Use, Deviation? Yes	ISO 80369-7-2016, Small-bore connectors for liquids and gases in healthcare applications -- Part 7: Connectors for intravascular or hyp	
13 ☒	14-497	General Use	If General Use, Deviation? Yes	ASTM F1980-2016, Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices	

(b)(4)

To add another row for Section J, please click on the button to the right. May be repeated as needed.
(To remove a particular row, please click on the "X" button at the beginning of the row.)

Add Row/Standard

SECTION K**UTILIZATION OF CDRH GUIDANCE DOCUMENTS**

How to fill out this section:

Title: Enter the title of the guidance documents used in the preparation of your premarket submission. CDRH guidance documents can be found at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>.

Entries for Utilization of CDRH Guidance Documents

	Title of Guidance Document
1 ☒	The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)], Guidance for Industry and Food and Drug Administration Staff, July 28, 2014
2 ☒	Recommended Content and Format of Non-Clinical Bench Performance Testing Information in Premarket Submissions, Guidance for Industry and Food and Drug Administration Staff, December 20, 2019
3 ☒	Providing Regulatory Submissions for Medical Devices in Electronic Format - Submissions under Section 745(b) of the Federal Food, Drug, and Cosmetic Act - Guidance for Industry and Food and Drug Administration Staff
4 ☒	Refuse to Accept Policy for 510(k)s - Guidance for Industry and Food and Drug Administration Staff, September 13, 2019
5 ☒	Peripheral Percutaneous Transluminal Angioplasty (PTA) and Specialty Catheters - Premarket Notification (510(k)) Submissions, Draft Guidance for Industry and Food and Drug Administration Staff, January 13, 2020
6 ☒	Deciding When to Submit a 510(k) for a Change to an Existing Device, Guidance for Industry and Food and Drug Administration Staff, October 25, 2017

7 The Special 510(k) Program - Guidance for Industry and Food and Drug Administration Staff, September 13, 2019.

To add another row for Section K, please click on the button to the right. May be repeated as needed.
(To remove a particular row, please click on the "X" button at the beginning of the row.)

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

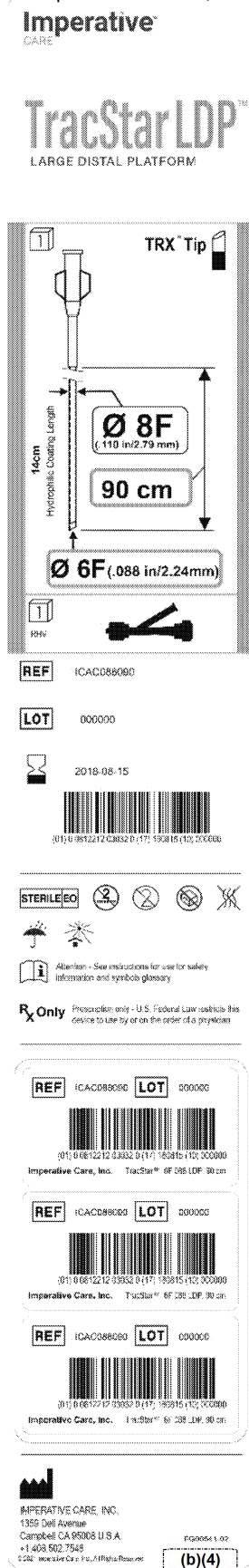
DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average .5 hours 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
PRASaff@fda.hhs.gov

"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 number."

Records processed under FOIA Request 2023-10349; Released by CDRH on 09-19-2024



Indications for Use

(b)(4)

Dear Ms. Ellis,

(b)(4)

Regards,

Leigh Anderson

Biomedical Engineer

Neurointerventional Devices Team

DHT5A: Division of Neurosurgical, Neurointerventional and Neurodiagnostic Devices

OHT5: Office of Neurological and Physical Medicine Devices

Office of Product Evaluation and Quality

CDRH | Food and Drug Administration

White Oak, Bldg. 66, Rm. 4276 | 10903 New Hampshire Avenue | Silver Spring, MD 20993

Ph: 301-796-5613

leigh.anderson@fda.hhs.gov<mailto:leigh.anderson@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?ID=1712&S=E>

THIS MESSAGE IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review, disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify the sender by e-mail or phone.



imperativecare.com
1359 Dell Avenue
Campbell, CA 95008

W: +1 669.235.8155
F: +1 669.265.0412
E: info@imperativecare.com

July 15, 2021

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – W066-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Attn: Neuro-interventional Devices Branch
Division of Neurological and Physical Medicine Devices
Office of Device Evaluation

RE: Special 510(k) Notification, Imperative Care Large Distal Platform (LDP) Catheters – Changes Made Under Design Controls

Enclosed is a Special 510(k) for proposed design and manufacturing modifications for the Imperative Care LDP catheters cleared under 510(k) K203764. Modifications to the catheter include dimensional updates, additional axial and radial reinforcements (b)(4) and manufacturing process improvements.

The Imperative Care LDP Catheters are Class II devices per 21 CFR 870.1250, Product Code QJP and DQY. The LDP Catheters included in this premarket notification are listed in the following table:

Trade Name (Proprietary Name)	Model Number	Size (ID x Working Length)
Zoom™ 88 Large Distal Platform	ICTC088100	0.088" x100cm
	ICTC088110	0.088" x110cm
TracStar™ Large Distal Platform	ICAC088080	0.088" x80cm
	ICAC088090	0.088" x90cm
	ICAC088095	0.088" x95cm
	ICAC088105	0.088" x105cm

To facilitate the review of this Special 510(k) notification, this submission has been formatted in accordance with the guidelines presented in the FDA guidance documents titled:



- *The Special 510(k) Program: Guidance for Industry and FDA Staff* issued September 13, 2019
- *Refuse to Accept Policy for 510(k)s: Guidance for Industry and FDA Staff* issued September 13, 2019
- *Recommended Content and Format of Non-Clinical Bench Performance Testing Information in Premarket Submissions* issued December 20, 2019

As required by the Medical Device User Fee and Modernization Act (MDUFA), a Medical Device User Fee has been electronically submitted. A copy of the Medical Device User Fee Cover Sheet is included in Section 1.0 of this submission.

One electronic copy (eCopy) of this submission is provided per FDA Guidance Document *eCopy Program for Medical Device Submissions Guidance for Industry and Food and Drug Administration Staff* issued April 27, 2020. The existence of this Premarket Notification is confidential, and the protection afforded to such confidential information by 21 CFR 807.95 (b), 18 USC 1905, 21 USC 331 (I), 5 USC 552, and other applicable laws is hereby claimed.

Your consideration of this Special 510(k) notification is appreciated. Should you have any questions or require further information, please contact me at (408) 857-0934 or via email at kellis@imperativecare.com. In my absence, please contact Nora Hadding, Senior Vice President, Clinical Affairs, Regulatory Affairs, and Quality Assurance at (b)(6) or via email at nhadding@imperativecare.com.

Sincerely,

(b)(6)

Kristin Ellis

Regulatory Affairs Manager

Imperative Care Inc.

Cc: Nora Hadding, Senior Vice President, Clinical Affairs, Regulatory Affairs, and Quality Assurance



Contains Nonbinding Recommendations

Print Form

510(k) Acceptance Checklist

Not for use with Third Party 510(k)s

Choose Submission Type: ☐ Traditional ☐ Abbreviated ☒ **Special**

(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) #: K212224

Date Received by DCC: Jul 16, 2021

Lead Reviewer: Leigh Anderson

Center: CDRH

Office: OHT 5

Division: DHT5A

Decision:

☒ Accept. If Accept, notify submitter.

☐ Refuse to Accept. If Refuse to Accept, notify submitter electronically and include a copy of this checklist.

Is an Addendum attached?: ☐ Yes ☒ No Click paperclip icon on the left panel if Addendum is attached.

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).

Special 510(k) Factors

(See "The Special 510(k) Program," available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/special-510k-program>).

Please complete the below questions to determine if the 510(k) is appropriate for review as a Special 510(k). Complete the Refuse to Accept Checklist for a Traditional 510(k) if submission is converted.

	Yes	No
1) 510(k) is submitted to modify a legally marketed device (predicate) AND the Special 510(k) submission is submitted by the manufacturer legally authorized to market the predicate device.	☒	☐
Comments:		
2. Performance data are needed to evaluate the change. If a manufacturer determines under their design control procedures that no additional verification or validation testing is necessary to evaluate a change, manufacturers may submit these changes as a Special 510(k) with a clear rationale supporting their conclusion that no performance data are necessary. When FDA does not agree with the manufacturer's assessment, FDA intends to continue with the additional Special 510(k) factors.	☒	☐
Comments:		
3) There is a well-established method to evaluate the change. Well-established methods include those used in the previously cleared 510(k), an FDA-recognized consensus standard or FDA guidance document, qualified medical device development tools (MDDTs), are widely available and accepted, or found acceptable through a different premarket submission by the same manufacturer of the predicate.	☒	☐
Comments:		

4) The data can be reviewed in a summary or risk analysis format. The results from verification and validation associated with design or labeling changes should be able to be placed in a summary or risk analysis format without losing information necessary to support SE. Complete test reports should not be submitted in a Special 510(k). If complete test reports are submitted, FDA intends to assess whether the information can be reviewed in a summary format before converting to a Traditional 510(k).



Comments:

Is the submission appropriate for review as a Special 510(k)? Answer Yes if the change was submitted by the manufacturer of the predicate, well-established methods are available for any performance data necessary, and performance data can be reviewed in a summary or risk analysis format.

- ☒ Yes, submission is appropriate for a Special 510(k). Continue checklist below.
- ☐ No, submission is not appropriate for a Special 510(k). Discontinue this RTA checklist, convert to a Traditional, and apply the Traditional checklist.

*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)	☒	☐	

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.

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. Records processed under FOIA Request 2023-10349; Released by CDRH on 09-19-2024					
	Yes	No	N/A	Comment	*Page #
*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.					
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], available at https://www.fda.gov/media/72421/download):				☐	
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" available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/alternative-certain-prescription-device-labeling-requirements) See recommended format. (https://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(l). See recommended format. (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm142707.htm)	☒	☐		☐	
6) Submission is a Class III 510(k) device. See recommended content (https://www.fda.gov/medical-devices/premarket-notification-510k/premarket-notification-class-iii-certification-and-summary).	☐		☒	☐	
7) 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), Q-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.	☐	☐	☒		
8) The submission utilizes voluntary consensus standard(s) (See section 514(c) of the FD&C Act). This includes both FDA-recognized and non-recognized consensus standards.	☒		☐	☐	
a) The submission cites FDA-recognized voluntary consensus standard(s)	☒		☐		

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. Records processed under FOIA Request 2023-10349; Released by CDRH on 09-19-2024					
*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 #
i) The submission includes a Declaration of Conformity (DOC) as outlined in FDA's guidance " Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices ," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/appropriate-use-voluntary-consensus-standards-premarket-submissions-medical-devices OR If citing general use of a standard as noted in FDA's guidance " Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices ," the basis of such use is included along with the underlying information or data that supports how the standard was used.	☒	☐			
b) The submission cites non-FDA-recognized voluntary consensus standard(s)	☐		☒		
Combination Product Provisions - Per 503(g) of the FD&C Act. Select "N/A" if the product is not a combination product. 21 CFR 3.2(e). The remaining criteria in this section will be omitted from the checklist if "N/A" is selected. If you are unsure if the product is a combination product, consult with the CDRH Product Jurisdiction Officer or CBER Product Jurisdiction Officer.					
			☒		
B. Device Description					
11) The device has a device-specific guidance document, special controls , and/or requirements in a device-specific classification regulation regarding the device description that is applicable to the subject device.	☐		☒	☐	
12) Descriptive information is present and consistent within the submission (e.g., the device description section is consistent with the device description in the labeling).	☒	☐		☐	
13) 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.	☒	☐	☐		
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).	☒	☐			
14) A detailed description of all device modification(s) including rationale for each modification. <i>When labeling or specific technological characteristics (e.g., materials, dimensions) are unchanged in comparison to the predicate, the submission should clearly state that no changes were made.</i>	☒	☐		☐	
15) Device is intended to be marketed with accessories and/or as part of a system.	☒		☐	☐	

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. Records processed under FOIA Request 2023-10349; Released by CDRH on 09-19-2024					
*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) Submission includes a list of all accessories to be marketed with the subject device.	☒	☐			
b) Submission includes a description (as detailed in item 13a, 13b and 13d above) of each component or accessory.	☒	☐	☐		
c) A 510(k) number is provided for each accessory that received a prior 510(k) clearance AND A statement is provided that identifies accessories that have not received prior 510(k) clearance.	☒	☐			
C. Substantial Equivalence Discussion					
16) 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, classification regulation reference, if exempt (e.g., 21 CFR 872.3710) or statement that the predicate is a preamendment device). For predicates that are preamendments devices, information is provided to document preamendments status. <i>Information regarding <u>documenting preamendment status</u> is available online. (https://www.fda.gov/medical-devices/quality-and-compliance-medical-devices/preamendment-status)</i>	☒	☐			
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).	☒	☐			
17) 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)] <i>See the FDA guidance document "<u>The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]</u>," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/510k-program-evaluating-substantial-equivalence-premarket-notifications-510k for more information on comparing intended use and technological characteristics.</i>				☐	
a) Indications for Use	☒	☐			
b) Technology, including technical specifications, features, materials, and principles of operation	☒	☐			
D. Design Control Activities					
18) Design Control Activities Summary includes all of the following:				☐	
a) Identification of Risk Analysis methods(s) used to assess the impact of the modification on the device and its components AND the results of the analysis.	☒	☐			
b) Identification of the device change(s).	☒	☐			
c) Identification of all risks associated with each device change, including identification of risks that are considered new because of the change; and.	☒	☐			
d) Risk control measures to mitigate identified risks (e.g., labeling verification)	☒	☐			

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. Records processed under FOIA Request 2023-10349; Released by CDRH on 09-19-2024					
*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 #
e) Based on the Risk Analysis, an identification of the verification and/or validation activities required, to comply with 21 CFR 820.30. This identification includes a summary of test methods (including any protocol deviations), acceptance criteria, results in a summary or risk analysis format (e.g., basic descriptive statistics, where appropriate), and why each is adequate to establish substantial equivalence. If unchanged from a previous premarket submission, the manufacturer references the location of protocols and acceptance criteria by providing a submission and section numbers.	☒	☐			
i) For non-standardized test methods only: A reference to the protocol used for the existing device with an identification of any differences (e.g., protocol, test conditions, pre-defined acceptance criteria, sample size) from the previous 510(k). If protocol changes were made, the results summary describes why the test methods, acceptance criteria, and results support SE.	☒	☐			
f) A signed statement by the manufacturer's designated individual(s) responsible for design control activities. Both items must be present to answer "Yes." i. Statement that, as required by the risk analysis, all verification and validation activities were performed by designated individual(s) and the results demonstrated that the predetermined acceptance criteria were met. ii. Statement that the submitter has complied and not currently in violation of the design control procedure requirements as specified in <u>21 CFR 820.30</u> and the records are available for review upon request.	☒	☐			
E. Proposed Labeling (see also <u>21 CFR part 801</u> and <u>809</u> as applicable)					
19) Submission includes proposed package labels and labeling (e.g., instructions for use, package insert, operator's manual).	☒	☐		☐	
a) All changes in proposed labeling resulting from device modification(s) are highlighted or prominently identified. <i>FDA recommends clean and redlined copies be provided.</i>	☒	☐			

Digital Signature Concurrence Table

Records processed under FOIA Request 2023-10349; Released by CDRH on 09-19-2024

Reviewer Sign-Off

Leigh B.
Anderson -S

Digitally signed by Leigh
B. Anderson -S
Date: 2021.07.28 09:11:41
-04'00'

Management Sign-Off
(digital signature
optional)*

* Management review of checklist and concurrence with with decision required.

Dear Ms. Ellis,

Thank you for your email and update regarding K212224.

Regards,

Leigh Anderson

Biomedical Engineer

Neurointerventional Devices Team

DHT5A: Division of Neurosurgical, Neurointerventional and Neurodiagnostic Devices

OHT5: Office of Neurological and Physical Medicine Devices

Office of Product Evaluation and Quality

CDRH | Food and Drug Administration

White Oak, Bldg. 66, Rm. 4276 | 10903 New Hampshire Avenue | Silver Spring, MD 20993

Ph: 301-796-5613

leigh.anderson@fda.hhs.gov<mailto:leigh.anderson@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?ID=1712&S=E>

THIS MESSAGE IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review, disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify the sender by e-mail or phone.

From: Kristin Ellis <kellis@imperativecare.com>

Sent: Monday, August 30, 2021 1:24 PM

To: Anderson, Leigh <Leigh.Anderson@fda.hhs.gov>

Subject: [EXTERNAL] RE: K212224 is on Hold Pending Your Response

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Good afternoon Ms. Anderson,

I apologize for not responding sooner, I acknowledge the receipt of the request for additional information. It is my intention to provide a response to you this week.

Kind regards,

Kristin Ellis

Regulatory Affairs Manager

[cid:image001.png@01D79FD5.729496F0]

M: +1.408.857.0934

E: kellis@imperativecare.com<<mailto:kellis@imperativecare.com>>

[imperativecare.com](http://www.imperativecare.com/)<<http://www.imperativecare.com/>> |
[LinkedIn](https://www.linkedin.com/company/imperativecare/)<<https://www.linkedin.com/company/imperativecare/>> |
[Twitter](https://twitter.com/imperative_care)<https://twitter.com/imperative_care> |
[YouTube](https://www.youtube.com/channel/UCOXtDHTSq28ZgSHkgtwPhyA)<<https://www.youtube.com/channel/UCOXtDHTSq28ZgSHkgtwPhyA>>

1359 Dell Avenue, Campbell, CA 95008

www.imperativecare.com<<http://www.imperativecare.com/>>

From: Leigh Anderson [LEIGH.ANDERSON]
<leigh.anderson@fda.hhs.gov<<mailto:leigh.anderson@fda.hhs.gov>>>

Sent: Wednesday, August 4, 2021 12:45 PM

To: Kristin Ellis <kellis@imperativecare.com<<mailto:kellis@imperativecare.com>>>

Cc: Leigh Anderson [LEIGH.ANDERSON]
<leigh.anderson@fda.hhs.gov<<mailto:leigh.anderson@fda.hhs.gov>>>

Subject: K212224 is on Hold Pending Your Response

August 4, 2021

We have reviewed your submission. Please see attached.

If you have any questions, please contact the lead reviewer assigned to your submission, Leigh Anderson.

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

Records processed under FOIA Request 2023-10349; Released by CDRH on 09-19-2024

**Imperative**
CARE**PRODUCT SPECIFICATION,
TRACSTAR & ZOOM
CATHETERS (b)(4)**

Doc. #

Rev.

DCO

(b)(4)**(b)(4)**

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

Dear Ms. Ellis,

Thank you for your email.

Our review tracking system indicates that today is day 31 of FDA's review clock for K212224. The submission is still under review at this time. If we have additional questions, we will reach out as soon as possible.

Regards,

Leigh Anderson
Biomedical Engineer
Neurointerventional Devices Team
DHTSA: Division of Neurosurgical, Neurointerventional and Neurodiagnostic Devices
OHTS: Office of Neurological and Physical Medicine Devices
Office of Product Evaluation and Quality
CDRH | Food and Drug Administration
White Oak, Bldg. 66, Rm. 4276 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-5613
leigh.anderson@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?ID=1712&S=E>

THIS MESSAGE IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review, disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify the sender by e-mail or phone.

From: Kristin Ellis <kellis@imperativecare.com>
Sent: Tuesday, September 14, 2021 11:48 AM
To: Anderson, Leigh <Leigh.Anderson@fda.hhs.gov>
Cc: Nora Hadding <nhadding@imperativecare.com>
Subject: [EXTERNAL] K212224 Review Status

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Good morning Ms. Anderson,

I hope this email finds you well. I am contacting you with regards to the review status of K212224. With the request for additional information hold and the Labor Day holiday, I am unsure of the review clock day count. I believe the clock is currently at Day 32. Can you please confirm if this is correct or if not, what date is the end of the review cycle?

Additionally, please let me know if there is any further information you require to complete the review.

Kind regards,

Kristin Ellis
Regulatory Affairs Manager



M: +1.408.857.0934
E: kellis@imperativecare.com
imperativecare.com | [LinkedIn](#) | [Twitter](#) | [YouTube](#)
1359 Dell Avenue, Campbell, CA 95008
www.imperativecare.com

Dear Ms. Ellis,

Our goal is to complete review of the response within 30 days of receipt, which shows to be October 2, 2021, in our document tracking system.

Regards,

Leigh Anderson

Biomedical Engineer

Neurointerventional Devices Team

DHT5A: Division of Neurosurgical, Neurointerventional and Neurodiagnostic Devices

OHT5: Office of Neurological and Physical Medicine Devices

Office of Product Evaluation and Quality

CDRH | Food and Drug Administration

White Oak, Bldg. 66, Rm. 4276 | 10903 New Hampshire Avenue | Silver Spring, MD 20993

Ph: 301-796-5613

leigh.anderson@fda.hhs.gov<mailto:leigh.anderson@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?ID=1712&S=E>

THIS MESSAGE IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review, disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify the sender by e-mail or phone.

From: Kristin Ellis <kellis@imperativecare.com>

Sent: Tuesday, September 14, 2021 12:45 PM

To: Anderson, Leigh <Leigh.Anderson@fda.hhs.gov>

Cc: Nora Hadding <nhadding@imperativecare.com>; K212224@docs.fda.gov

Subject: RE: [EXTERNAL] K212224 Review Status

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Dear Ms. Anderson,

Thank you for the correction of the review clock day. Can you please provide me with the submission timing review goal for this Special 510(k)? This would be helpful for our planning purposes.

Kind regards,

Kristin Ellis

Regulatory Affairs Manager

[cid:image001.png@01D7A988.6A8582A0]

M: +1.408.857.0934

E: kellis@imperativecare.com<<mailto:kellis@imperativecare.com>>

[imperativecare.com](http://www.imperativecare.com/)<<http://www.imperativecare.com/>> |
[LinkedIn](https://www.linkedin.com/company/imperativecare/)<<https://www.linkedin.com/company/imperativecare/>> |
[Twitter](https://twitter.com/imperative_care)<https://twitter.com/imperative_care> |
[YouTube](https://www.youtube.com/channel/UCOXtDHTSq28ZgSHkgtwPhyA)<<https://www.youtube.com/channel/UCOXtDHTSq28ZgSHkgtwPhyA>>

1359 Dell Avenue, Campbell, CA 95008

www.imperativecare.com<<http://www.imperativecare.com/>>

From: Anderson, Leigh <Leigh.Anderson@fda.hhs.gov<<mailto:Leigh.Anderson@fda.hhs.gov>>>

Sent: Tuesday, September 14, 2021 9:22 AM

To: Kristin Ellis <kellis@imperativecare.com<<mailto:kellis@imperativecare.com>>>

Cc: Nora Hadding <nhadding@imperativecare.com<<mailto:nhadding@imperativecare.com>>>;
K212224@docs.fda.gov<<mailto:K212224@docs.fda.gov>>

Subject: RE: [EXTERNAL] K212224 Review Status

Dear Ms. Ellis,

Thank you for your email.

Our review tracking system indicates that today is day 31 of FDA's review clock for K212224. The submission is still under review at this time. If we have additional questions, we will reach out as soon as possible.

Regards,

Leigh Anderson

Biomedical Engineer

Neurointerventional Devices Team

DHT5A: Division of Neurosurgical, Neurointerventional and Neurodiagnostic Devices

OHT5: Office of Neurological and Physical Medicine Devices

Office of Product Evaluation and Quality

CDRH | Food and Drug Administration

White Oak, Bldg. 66, Rm. 4276 | 10903 New Hampshire Avenue | Silver Spring, MD 20993

Ph: 301-796-5613

leigh.anderson@fda.hhs.gov<<mailto:leigh.anderson@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?ID=1712&S=E><<https://nam12.safelinks.protocol.outlook.com/?url=https%3A%2F%2Fwww.research.net%2F%2Fcdrhcustomerservice%3FID%3D1712%26S%3DE&data=04%7C01%7Ckellis%40imperativecare.com%7C41d7389c973f4ad8b56608d9779bb9f6%7Cf9bc67a2b9bd4bcc974aec60ef533fdc%7C0%7C0%7C637672333015015148%7CUnknown%7CTWFpbGZsb3d8eyJWIjojMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6IklhaWwiLCJXVCi6Mn0%3D%7C1000&sdata=c>>

THIS MESSAGE IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review, disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify the sender by e-mail or phone.

From: Kristin Ellis <kellis@imperativecare.com<mailto:kellis@imperativecare.com>>
Sent: Tuesday, September 14, 2021 11:48 AM
To: Anderson, Leigh <Leigh.Anderson@fda.hhs.gov<mailto:Leigh.Anderson@fda.hhs.gov>>
Cc: Nora Hadding <nhadding@imperativecare.com<mailto:nhadding@imperativecare.com>>
Subject: [EXTERNAL] K212224 Review Status

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Good morning Ms. Anderson,

I hope this email finds you well. I am contacting you with regards to the review status of K212224. With the request for additional information hold and the Labor Day holiday, I am unsure of the review clock day count. I believe the clock is currently at Day 32. Can you please confirm if this is correct or if not, what date is the end of the review cycle?

Additionally, please let me know if there is any further information you require to complete the review.

Kind regards,

Kristin Ellis

Regulatory Affairs Manager

[cid:image001.png@01D7A988.6A8582A0]

M: +1.408.857.0934

E: kellis@imperativecare.com<mailto:kellis@imperativecare.com>

imperativecare.com<http://www.imperativecare.com/> |
LinkedIn<https://nam12.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.linkedin.com%2Fcompany%2Fimperativecare%2F&data=04%7C01%7Ckellis%40imperativecare.com%7C41d7389c973f4ad8b56608d9779bb9f6%7Cf9bc67a2b9bd4bcc974aec60ef533fdc%7C0%7C0%7C637672333015015148%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6IklhaWwiLCJXVCi6Mn0%3D%7C1000&sdata=Y9Tbi5VmJZ23RCWbX1lqAjXWiaGY5qBvwqqDjOD9hpw%3D&reserved=0> |
Twitter<https://nam12.safelinks.protection.outlook.com/?url=https%3A%2F%2Ftwitter.com%2Fimperative_care&data=04%7C01%7Ckellis%40imperativecare.com%7C41d7389c973f4ad8b56608d9779bb9f6%7Cf9bc67a2b9bd4bcc974aec60ef533fdc%7C0%7C0%7C637672333015015148%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6IklhaWwiLCJXVCi6Mn0%3D%7C1000&sdata=17iP23PU%2F9LwaYyBHW4gml5fvYnRetNO%2Bw45kIlzi0Y%3D&reserved=0> |
YouTube<https://www.youtube.com/channel/UCOXtDHTSq28ZgSHkgtwPhyA>

1359 Dell Avenue, Campbell, CA 95008

Indications for Use

510(k) Number (if known)

K212224

Device Name

TracStar LDP Large Distal Platform

Zoom 88 Large Distal Platform

Indications for Use (Describe)

The TracStar LDP Large Distal Platform is indicated for the introduction of interventional devices into the peripheral, coronary, and neuro vasculature.

The Zoom 88 Large Distal Platform is indicated for the introduction of interventional devices into the peripheral, coronary, and neuro vasculature.

Type of Use (Select one or both, as applicable)

☒ Prescription Use (Part 21 CFR 801 Subpart D)

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

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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

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

The burden time for this collection of information is estimated to average 79 hours 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
PRASStaff@fda.hhs.gov

"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 number."

Dear Ms. Anderson,

Attached please find the response to FDA's Interactive Request for the

(b)(4)

Please let me know if you have further questions or need any further clarification.

Kind regards,

Kristin Ellis

Regulatory Affairs Manager



M: +1.408.857.0934

E: kellis@imperativecare.com

imperativecare.com | [LinkedIn](#) | [Twitter](#) | [YouTube](#)

1359 Dell Avenue, Campbell, CA 95008

www.imperativecare.com

From: Anderson, Leigh <Leigh.Anderson@fda.hhs.gov>

Sent: Friday, July 23, 2021 7:38 AM

To: Kristin Ellis <kellis@imperativecare.com>

Cc: K212224@docs.fda.gov

Subject: K212224 - Interactive Request (b)(4) Please Reply by Mon Jul 26)

Dear Ms. Ellis,

I am lead reviewer for K212224 for the TracStar and Zoom 88 Large Distal Platform Catheters. We are still early in our review and primarily in the administrative RTA review phase. We have noticed that the following (b)(4)

We request that you provide a response to the following items via email by Monday, July 26 to facilitate our review. If you have concerns with the proposed timeline, please let me know.

FDA Request:

(b)(4)

Regards,

Leigh Anderson
Biomedical Engineer
Neurointerventional Devices Team
DHT5A: Division of Neurosurgical, Neurointerventional and Neurodiagnostic Devices
OHT5: Office of Neurological and Physical Medicine Devices
Office of Product Evaluation and Quality
CDRH | Food and Drug Administration
White Oak, Bldg. 66, Rm. 4276 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-5613
leigh.anderson@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?ID=1712&S=E>

THIS MESSAGE IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review, disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify the sender by e-mail or phone.

(b)(4)

(b)(4)

(b)(4)

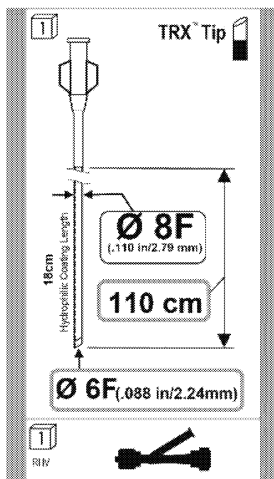
(b)(4)

(b)(4)

(b)(4)

(b)(4)

Records processed under FOIA Request 2023-10349; Released by CDRH on 09-19-2024

Imperative
CARE**Zoom™ 88**
LARGE DISTAL PLATFORM**REF** ICTC088110**LOT** 000000 2018-08-15

(01) 0 081272 00000 8 (17) 300815 (10) 000000

STERILE **Attention:** See instructions for use for safety information and symbols glossary.**Rx Only** Prescription only. U.S. Federal Law restricts this device to use by or on the order of a physician.**REF** ICTC088110 **LOT** 000000

(01) 0 081272 00000 8 (17) 300815 (10) 000000

Imperative Care, Inc. ZOOM™ 88 8F 088 LDP, 110 cm

REF ICTC088110 **LOT** 000000

(01) 0 081272 00000 8 (17) 300815 (10) 000000

Imperative Care, Inc. ZOOM™ 88 6F 086 LDP, 110 cm

REF ICTC088110 **LOT** 000000

(01) 0 081272 00000 8 (17) 300815 (10) 000000

Imperative Care, Inc. ZOOM™ 88 8F 088 LDP, 110 cm

IMPERATIVE CARE, INC.
1369 Dell Avenue
Campbell CA 95008 U.S.A.
+1 408.502.7548

© 2018 Imperative Care, Inc., All Rights Reserved

FD000554-02

(b)(4)

Dear Ms. Ellis,

Thank you for confirming receipt and for working with us interactively to address questions during review.

Regards,

Leigh Anderson

Biomedical Engineer

Neurointerventional Devices Team

DHT5A: Division of Neurosurgical, Neurointerventional and Neurodiagnostic Devices

OHT5: Office of Neurological and Physical Medicine Devices

Office of Product Evaluation and Quality

CDRH | Food and Drug Administration

White Oak, Bldg. 66, Rm. 4276 | 10903 New Hampshire Avenue | Silver Spring, MD 20993

Ph: 301-796-5613

leigh.anderson@fda.hhs.gov<mailto:leigh.anderson@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?ID=1712&S=E>

THIS MESSAGE IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review, disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify the sender by e-mail or phone.

From: Kristin Ellis <kellis@imperativecare.com>

Sent: Monday, September 20, 2021 2:05 PM

To: Anderson, Leigh <Leigh.Anderson@fda.hhs.gov>

Subject: [EXTERNAL] RE: K212224/S001 Review Complete

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Dear Ms. Anderson,

Thank you for the completion of the review. I appreciate your efforts and the answers to all of my questions.

Kind regards,

Kristin Ellis

Regulatory Affairs Manager

[cid:image001.png@01D7AE2B.39873CF0]

M: +1.408.857.0934

E: kellis@imperativecare.com<<mailto:kellis@imperativecare.com>>

[imperativecare.com](http://www.imperativecare.com/)<<http://www.imperativecare.com/>> |
[LinkedIn](https://www.linkedin.com/company/imperativecare/)<<https://www.linkedin.com/company/imperativecare/>> |
[Twitter](https://twitter.com/imperative_care)<https://twitter.com/imperative_care> |
[YouTube](https://www.youtube.com/channel/UCOXtDHTSq28ZgSHkgtwPhyA)<<https://www.youtube.com/channel/UCOXtDHTSq28ZgSHkgtwPhyA>>

1359 Dell Avenue, Campbell, CA 95008

www.imperativecare.com<<http://www.imperativecare.com/>>

From: Leigh Anderson [LEIGH.ANDERSON]
<leigh.anderson@fda.hhs.gov<<mailto:leigh.anderson@fda.hhs.gov>>>

Sent: Monday, September 20, 2021 11:00 AM

To: Kristin Ellis <kellis@imperativecare.com<<mailto:kellis@imperativecare.com>>>

Cc: Leigh Anderson [LEIGH.ANDERSON]
<leigh.anderson@fda.hhs.gov<<mailto:leigh.anderson@fda.hhs.gov>>>

Subject: K212224/S001 Review Complete

September 20, 2021

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, Leigh Anderson.

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

510(k) Summary

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

Dear Ms. Ellis,

Thank you for your quick review and reply. We will use the latest versions I sent by email at this point moving forward.

If we have additional questions, we will reach out to you.

Regards,

Leigh Anderson

Biomedical Engineer

Neurointerventional Devices Team

DHT5A: Division of Neurosurgical, Neurointerventional and Neurodiagnostic Devices

OHT5: Office of Neurological and Physical Medicine Devices

Office of Product Evaluation and Quality

CDRH | Food and Drug Administration

White Oak, Bldg. 66, Rm. 4276 | 10903 New Hampshire Avenue | Silver Spring, MD 20993

Ph: 301-796-5613

leigh.anderson@fda.hhs.gov<mailto:leigh.anderson@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?ID=1712&S=E>

THIS MESSAGE IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review, disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify the sender by e-mail or phone.

From: Kristin Ellis <kellis@imperativecare.com>

Sent: Thursday, September 9, 2021 5:19 PM

To: Anderson, Leigh <Leigh.Anderson@fda.hhs.gov>

Cc: K212224@docs.fda.gov

Subject: [EXTERNAL] RE: K212224 - Interactive Request -

(b)(4)

(b)(4)

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Dear Ms. Anderson,

(b)(4)

Kind regards,

Kristin Ellis

Regulatory Affairs Manager

[cid:image001.png@01D7A59F.1F5D99D0]

M: +1.408.857.0934

E: kellis@imperativecare.com<<mailto:kellis@imperativecare.com>>

[imperativecare.com](http://www.imperativecare.com/)<<http://www.imperativecare.com/>> |

LinkedIn<<https://www.linkedin.com/company/imperativecare/>> |

Twitter<https://twitter.com/imperative_care> |

YouTube<<https://www.youtube.com/channel/UCOXtDHTSq28ZgSHkgtwPhyA>>

1359 Dell Avenue, Campbell, CA 95008

www.imperativecare.com<<http://www.imperativecare.com/>>

From: Anderson, Leigh <Leigh.Anderson@fda.hhs.gov<<mailto:Leigh.Anderson@fda.hhs.gov>>>

Sent: Thursday, September 9, 2021 2:11 PM

To: Kristin Ellis <kellis@imperativecare.com<<mailto:kellis@imperativecare.com>>>

Cc: K212224@docs.fda.gov<<mailto:K212224@docs.fda.gov>>

Subject: K212224 - Interactive Request -

(b)(4)

(b)(4)

Dear Ms. Ellis,

(b)(4)

Regards,

Leigh Anderson

Biomedical Engineer

Neurointerventional Devices Team

DHT5A: Division of Neurosurgical, Neurointerventional and Neurodiagnostic Devices

OHT5: Office of Neurological and Physical Medicine Devices

Office of Product Evaluation and Quality

CDRH | Food and Drug Administration

White Oak, Bldg. 66, Rm. 4276 | 10903 New Hampshire Avenue | Silver Spring, MD 20993

Ph: 301-796-5613

leigh.anderson@fda.hhs.gov<<mailto:leigh.anderson@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?ID=1712&S=E<https://nam12.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.research.net%2Fs%2Fcdrhcustomerservice%3FID%3D1712%26S%3DE&data=04%7C01%7Ckellis%40imperativecare.com%7C6f34f4d4cbd740eca5f108d973d68b7e%7Cf9bc67a2b9bd4bcc974aec60ef533fdc%7C0%7C0%7C637668187905926085%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6IklhaWwiLCJXVCI6Mn0%3D%7C1000&sdata=kgy3WYuF8P8xTlFFKqG1R6uqn5WNj2UFuuYNBuCLVQs%3D&reserved=0>

THIS MESSAGE IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review, disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify the sender by e-mail or phone.

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

INSTRUCTIONS FOR USE

TracStar LDP™
LARGE DISTAL PLATFORM

Imperative™
CARE

DEVICE DESCRIPTION

The TracStar LDP™ Large Distal Platform™ (TracStar LDP) is a single lumen, braid and coil reinforced, variable stiffness catheter with a radiopaque marker and a lubricious hydrophilic coating on the distal 14 cm portion of the catheter. The TracStar LDP has an outer diameter of 0.110" (2.8 mm) and is offered in working lengths of 95 cm and 105 cm. Additional dimensions are included on the device labels. The TracStar LDP has a luer hub on the proximal end. The TracStar LDP is compatible with 8F or greater introducer sheaths and 0.038" or smaller guidewires. A support catheter may also be used to assist in accessing the target vasculature.

The TracStar LDP is packaged with an accessory Rotating Hemostasis Valve (RHV). The RHV is intended to be attached to the proximal hub of the TracStar LDP and used to control hemostasis during use with other devices.

INDICATIONS FOR USE

The TracStar LDP Large Distal Platform is indicated for the introduction of interventional devices into the peripheral, coronary, and neuro vasculature.

CONTRAINDICATIONS

There are no known contraindications.

WARNINGS

- The TracStar LDP should only be used by physicians who have received appropriate training in interventional techniques and are proficient in using guide sheaths and catheters.
- Extreme caution should be used if it is required that the TracStar LDP be advanced near or through any aneurysms or other vascular malformations.
- The distal portion of the catheter has a lubricious hydrophilic coating and should be hydrated per Step 7 with heparinized saline before inserting the catheter into the patient. Failure to abide by this warning may result in damage to the device coating, which may necessitate intervention or result in serious adverse events.

PRECAUTIONS

- Use prior to the "Use By" date specified on the product package.
- This device is intended for single use only. Do not resterilize or reuse. After use, dispose in accordance with hospital and/or local government policy.
- Do not use kinked or damaged devices. Do not use open or damaged packages.
- Do not use if the labeling is incomplete or illegible.
- Prior to use, ensure that the dimensions (e.g. diameter and length) of the TracStar LDP and accessory/adjunctive devices to be used in the procedure are compatible with each other and appropriate for the target vasculature.

INSTRUCTIONS FOR USE

TracStar LDP™
LARGE DISTAL PLATFORM

Imperative™
CARE

- To avoid the introduction of embolic fibers, do not use fabric/cloth/gauze to hydrate or wipe down the catheters. Catheters should be hydrated through short immersion in a bath of heparinized saline.
- Use the TracStar LDP in conjunction with fluoroscopic visualization.

Note: Sufficient shielding, reduced fluoroscopy times, and modified X-ray technical factors should be used when possible to limit patient and physician exposure to X-ray radiation doses.

- Exercise care when manipulating the device through tortuous anatomy. Do not advance or withdraw the TracStar LDP or accessory/adjunctive devices against resistance without careful assessment of the cause under fluoroscopy. If the cause cannot be determined, withdraw all devices as a single unit. Excessive manipulation or torqueing the device against resistance may result in damage to the vasculature or the device.
- Precautions to prevent or reduce clotting should be taken when any catheter is used in the vascular system. The use of systematic heparinization and heparinized sterile solution should be considered.
- Maintain a constant infusion of an appropriate flush solution. If using a heparinized flush solution, care should be taken to account for the additional heparin being administered via the flush solution. Failure to do so can result in coagulopathy and excessive bleeding at the access site.
- If flow through the device becomes restricted, do not attempt to clear the lumen by infusion. Remove and replace the device.
- Use of an introducer sheath is necessary to introduce the TracStar LDP into the patient's vasculature. Attempting to introduce the catheter without this introducer can result in kinking or other damage to the device.
- Hemostasis valves should be appropriately used throughout the procedure to minimize blood loss. Monitoring of intra-procedural blood loss throughout the procedure should also be performed to ensure that appropriate management may be instituted as necessary.
- Do not use automated high-pressure contrast injection equipment with the TracStar LDP as it may damage the device.

POTENTIAL ADVERSE EVENTS

Possible complications include, but are not limited to, the following:

- | | |
|--|--|
| • Acute occlusion, Ischemia | • Infection, Sepsis |
| • Unstable angina | • Intracranial hemorrhage |
| • Arrhythmia, including ventricular fibrillation | • Hypotension/Hypertension |
| • Death | • Acute myocardial infarction |
| • Distal embolization | • Infarction/Necrosis |
| • Emboli | • Neurological defects including stroke |
| • False aneurysm formation | • Vessel spasm, thrombosis, dissection, perforation, rupture |
| • Fever | • Drug reactions (e.g. coagulopathy, renal insufficiency/failure, allergic reaction) |
| • Access Site Complications (Hematoma or hemorrhage, sterile inflammation, granulomas) | |

This device is required to be used with fluoroscopy. Potential complications related to angiographic and fluoroscopic X-ray radiation doses include, but are not limited to: alopecia, burns ranging in severity

INSTRUCTIONS FOR USE

TracStar LDP™
LARGE DISTAL PLATFORM

Imperative™
CARE

from skin reddening to ulcers, cataracts, and delayed neoplasia. The probability of occurrence of complications may increase as procedure time and number of procedures increase.

DEVICE PREPARATION AND USE

1. Select an appropriate TracStar LDP based on distance from the access site to the target anatomy. Ensure that the diameter of the TracStar LDP is appropriate for the vasculature.
2. Select an appropriate support catheter based on the dimensions of the TracStar LDP being used, the target vessel, and the surrounding anatomy to help aid in accessing the target vessel.
3. Open the product pouch and place the pouch card into the sterile field. Exercise care when removing the pouch card from the product pouch to prevent damage to the device and accessories.
4. Remove the Rotating Hemostasis Valve (RHV) from the pouch card by removing it from the card tabs before gently lifting the TracStar LDP luer from the pouch card tab and removing the catheter shaft from the protective tubing.
5. Inspect the TracStar LDP and accessories for kinks or other damage. If damage is noted, do not use the device. Replace with an undamaged device.

Use Steps for the TracStar LDP Large Distal Platform

6. Attach the provided RHV to the luer of the TracStar LDP.
7. Hydrate the outer surface of the TracStar LDP and flush the lumen of the catheter and RHV with heparinized saline.

Note: To avoid the introduction of embolic fibers, do not use fabric/cloth/gauze to hydrate or wipe down the catheters. Catheters should be hydrated through short immersion in a bath of heparinized saline.
8. Open the RHV and advance support catheter + guidewire (≤ 0.038 " diameter) into the TracStar LDP until the distal tip of the support catheter is well past the distal tip of the TracStar LDP and then tighten the RHV to secure the support catheter in place. Do not overtighten the RHV as it could deform the support catheter lumen and prevent passage of a guidewire.
9. Gently insert the TracStar LDP/support catheter/guidewire assembly (device assembly) into the 8F or larger introducer sheath.

Note: Follow the introducer sheath manufacturer's instructions for use when performing this step.
10. Under fluoroscopy, advance the device assembly through the introducer sheath and into the patient's vasculature using conventional catheterization techniques.

Note: If injection through the TracStar LDP is necessary, remove the support catheter and guidewire and aspirate the TracStar LDP lumen prior to injection.
11. After gaining access to the desired vessel with the support catheter and guidewire, advance the TracStar LDP over the support catheter to the desired position.
12. Once the desired position is achieved, remove the support catheter and, if necessary, the guidewire.

INSTRUCTIONS FOR USE

TracStar LDP™
LARGE DISTAL PLATFORM

Imperative™
CARE

13. The TracStar LDP can be used as a conduit for other interventional and diagnostic agents to access the target vascular site and distal vessels.

Note: Ensure that the pressure for any fluids being injected through the TracStar LDP does not exceed 300 PSI. Exceeding this value can result in severe vascular trauma.

14. After the procedure has been completed, remove the TracStar LDP through the introducer sheath per standard procedure.
15. Discard the TracStar LDP appropriately per facility procedure.

PACKAGING

The TracStar LDP is placed inside a protective HDPE tube and then secured to a HDPE packaging card. Accessories included in the TracStar LDP packaging include a Rotating Hemostasis Valve (RHV). The packaging card is placed into a Nylon/Tyvek pouch which is thermally sealed to maintain sterility post sterilization.

The TracStar LDP is sterilized using Ethylene Oxide (EtO).

The TracStar LDP will remain sterile unless the pouch is opened, damaged, or the “Use By” date has passed.

MATERIALS

The TracStar LDP is not made with natural rubber latex.

STORAGE AND HANDLING

Keep dry. Keep away from sunlight. Store at room temperature.

SYMBOLS GLOSSARY

Standard Reference: ISO 15223-1 §5.1.5 Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements

Symbol	Definition
	Manufacturer
	Lot number
	Use by
	Attention - See instructions for use for safety information and symbols glossary

INSTRUCTIONS FOR USE

TracStar LDP™
LARGE DISTAL PLATFORM

Imperative™
CARE

	Catalogue number
	Sterilized by ethylene oxide
	Nonpyrogenic
	Prescription only – U.S. Federal Law restricts this device to use by or on the order of a physician
	Do not use if packaging is damaged
	Do not resterilize
	Do not reuse
	Contents (numeral indicates quantity of systems in package)
	Keep away from sunlight
	Keep dry

WARRANTY

Imperative Care, Inc. (“Imperative Care”) warrants that reasonable care has been used in the design and manufacture of this device. This warranty is in lieu of and excludes all other warranties not expressly set forth herein, whether expressed or implied by operation of law or otherwise, including, but not limited to, any implied warranties of merchantability or fitness for a particular use. Handling, storage, cleaning, and sterilization of this device as well as other factors relating to the patient, diagnosis, treatment, surgical procedures, and other matters beyond Imperative Care’s control directly affect the device and the results obtained from its use. Imperative Care’s obligation under this warranty is limited to the replacement of this device and Imperative Care shall not be liable for any incidental, consequential, or special loss, damage, or expense directly or indirectly arising from the use of this device. Imperative Care neither assumes, nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with this device. This warranty is valid only if the device is used in accordance with the manufacturer’s instructions, and the warranty is limited to the original user. Any sale or other transfer or use of the device covered by this warranty to or by a user other than the original user shall cause this warranty to terminate immediately. Imperative Care assumes no liability with respect to devices reused, reprocessed, or resterilized, or serviced, repaired or modified by any party.

INSTRUCTIONS FOR USE

TracStarLDP™
LARGE DISTAL PLATFORM

Imperative™
CARE

other than the original manufacturer, and makes no warranties, expressed or implied, including but not limited to merchantability or fitness for intended use, with respect to such devices.



IMPERATIVE CARE, INC.
1359 Dell Avenue
Campbell, CA 95008 U.S.A.
+1.408.502.7548

© 2020 Imperative Care, Inc. All Rights Reserved.

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

INSTRUCTIONS FOR USE

Zoom™ 88
LARGE DISTAL PLATFORM

Imperative™
CARE

DEVICE DESCRIPTION

The Zoom™ 88 Large Distal Platform™ catheters (Zoom 88) are single lumen, braid and coil reinforced, variable stiffness catheters with a radiopaque marker and a lubricious hydrophilic coating on the distal 18 cm portion of the catheter. The Zoom 88 has an outer diameter of 0.110" (2.8 mm) and is offered in a working length of 110 cm. Additional dimensions are included on the device label. The Zoom 88 has a luer hub on the proximal end. The Zoom 88 is compatible with 8F or greater introducer sheaths and 0.038" or smaller guidewires. A support catheter may also be used to assist in accessing the target vasculature.

The Zoom 88 is packaged with an accessory Rotating Hemostasis Valve (RHV). The RHV is intended to be attached to the proximal hub of the Zoom 88 and used to control hemostasis during use with other devices.

INDICATIONS FOR USE

The Zoom 88 Large Distal Platform is indicated for the introduction of interventional devices into the peripheral, coronary, and neuro vasculature.

CONTRAINDICATIONS

There are no known contraindications.

WARNINGS

- The Zoom 88 should only be used by physicians who have received appropriate training in interventional techniques and are proficient in using guide sheaths and catheters.
- Extreme caution should be used if it is required that the Zoom 88 be advanced near or through any aneurysms or other vascular malformations.
- The distal portion of the catheter has a lubricious hydrophilic coating and should be hydrated per Step 7 with heparinized saline before inserting the catheter into the patient. Failure to abide by this warning may result in damage to the device coating, which may necessitate intervention or result in serious adverse events.

PRECAUTIONS

- Use prior to the "Use By" date specified on the product package.
- This device is intended for single use only. Do not resterilize or reuse. After use, dispose in accordance with hospital and/or local government policy.
- Do not use kinked or damaged devices. Do not use open or damaged packages.
- Do not use if the labeling is incomplete or illegible.
- Prior to use, ensure that the dimensions (e.g. diameter and length) of the Zoom 88 and accessory/adjunctive devices to be used in the procedure are compatible with each other and appropriate for the target vasculature.
- To avoid the introduction of embolic fibers, do not use fabric/cloth/gauze to hydrate or wipe down the catheters. Catheters should be hydrated through short immersion in a bath of heparinized saline.

INSTRUCTIONS FOR USE

Zoom™ 88
LARGE DISTAL PLATFORM

Imperative™
CARE

- Use the Zoom 88 in conjunction with fluoroscopic visualization.

Note: Sufficient shielding, reduced fluoroscopy times, and modified X-ray technical factors should be used when possible to limit patient and physician exposure to X-ray radiation doses.

- Exercise care when manipulating the device through tortuous anatomy. **Do not** advance or withdraw the Zoom 88 or accessory/adjunctive devices against resistance without careful assessment of the cause under fluoroscopy. If the cause cannot be determined, withdraw all devices as a single unit. Excessive manipulation or torquing the device against resistance may result in damage to the vasculature or the device.
- Precautions to prevent or reduce clotting should be taken when any catheter is used in the vascular system. The use of systematic heparinization and heparinized sterile solution should be considered.
- Maintain a constant infusion of an appropriate flush solution. If using a heparinized flush solution, care should be taken to account for the additional heparin being administered via the flush solution. Failure to do so can result in coagulopathy and excessive bleeding at the access site.
- If flow through the device becomes restricted, do not attempt to clear the lumen by infusion. Remove and replace the device.
- Use of an introducer sheath is necessary to introduce the Zoom 88 into the patient's vasculature. Attempting to introduce the catheter without this introducer can result in kinking or other damage to the device.
- Hemostasis valves should be appropriately used throughout the procedure to minimize blood loss. Monitoring of intra-procedural blood loss throughout the procedure should also be performed to ensure that appropriate management may be instituted as necessary.
- Do not use automated high-pressure contrast injection equipment with the Zoom 88 as it may damage the device.

POTENTIAL ADVERSE EVENTS

Possible complications include, but are not limited to, the following:

- | | |
|--|--|
| • Acute occlusion, Ischemia | • Infection, Sepsis |
| • Unstable angina | • Intracranial hemorrhage |
| • Arrhythmia, including ventricular fibrillation | • Hypotension/Hypertension |
| • Death | • Acute myocardial infarction |
| • Distal embolization | • Infarction/Necrosis |
| • Emboli | • Neurological defects including stroke |
| • False aneurysm formation | • Vessel spasm, thrombosis, dissection, perforation, rupture |
| • Fever | • Drug reactions (e.g. coagulopathy, renal insufficiency/failure, allergic reaction) |
| • Access Site Complications (Hematoma or hemorrhage, sterile inflammation, granulomas) | |

This device is required to be used with fluoroscopy. Potential complications related to angiographic and fluoroscopic X-ray radiation doses include, but are not limited to: alopecia, burns ranging in severity from skin reddening to ulcers, cataracts, and delayed neoplasia. The probability of occurrence of complications may increase as procedure time and number of procedures increase.

INSTRUCTIONS FOR USE

Zoom™ 88
LARGE DISTAL PLATFORM

Imperative™
CARE

DEVICE PREPARATION AND USE

1. Select an appropriate Zoom 88 based on the distance from the access site to the target anatomy. Ensure that the diameter of the Zoom 88 is appropriate for the vasculature.
2. Select an appropriate support catheter based on the dimensions of Zoom 88 being used, the target vessel, and the surrounding anatomy to help aid in accessing the target vessel.
3. Open the product pouch and place the pouch card into the sterile field. Exercise care when removing the pouch card from the product pouch to prevent damage to the device and accessories.
4. Remove the Rotating Hemostasis Valve (RHV) from the pouch card by removing it from the card tabs before gently lifting the Zoom 88 luer from the pouch card tab and removing the catheter shaft from the protective tubing.
5. Inspect the Zoom 88 and accessories for kinks or other damage. If damage is noted, do not use the device. Replace with an undamaged device.

Use Steps for the Zoom 88 Large Distal Platform

6. Attach the provided RHV to the luer of the Zoom 88.
7. Hydrate the outer surface of the Zoom 88 and flush the lumen of the catheter and RHV with heparinized saline.

Note: To avoid the introduction of embolic fibers, do not use fabric/cloth/gauze to hydrate or wipe down the catheters. Catheters should be hydrated through short immersion in a bath of heparinized saline.
8. Open the RHV and advance support catheter + guidewire (≤ 0.038 " diameter) into the Zoom 88 until the distal tip of the support catheter is well past the distal tip of the Zoom 88 and then tighten the RHV to secure the support catheter in place. Do not overtighten the RHV as it could deform the support catheter lumen and prevent passage of a guidewire.
9. Gently insert the Zoom 88/support catheter/guidewire assembly (device assembly) into the 8F or larger introducer sheath.

Note: Follow the introducer sheath manufacturer's instructions for use when performing this step.
10. Under fluoroscopy, advance the device assembly through the introducer sheath and into the patient's vasculature using conventional catheterization techniques.

Note: If injection through the Zoom 88 is necessary, remove the support catheter and guidewire and aspirate the Zoom 88 lumen prior to injection.
11. After gaining access to the desired vessel with the support catheter and guidewire, advance the Zoom 88 over the support catheter to the desired position.
12. Once the desired position is achieved, remove the support catheter and, if necessary, the guidewire.

INSTRUCTIONS FOR USE

Zoom™ 88
LARGE DISTAL PLATFORM

Imperative™
CARE

13. The Zoom 88 can be used as a conduit for other interventional and diagnostic agents to access the target vascular site and distal vessels.

Note: Ensure that the pressure for any fluids being injected through the Zoom 88 does not exceed 300 PSI. Exceeding this value can result in severe vascular trauma.

14. After the procedure has been completed, remove the Zoom 88 through the introducer sheath per standard procedure.
15. Discard the Zoom 88 appropriately per facility procedure.

PACKAGING

The Zoom 88 is placed inside a protective HDPE tube and then secured to a HDPE packaging card. Accessories included in the Zoom 88 packaging include a Rotating Hemostasis Valve (RHV). The packaging card is placed into a Nylon/Tyvek pouch which is thermally sealed to maintain sterility post sterilization.

The Zoom 88 is sterilized using Ethylene Oxide (EtO).

The Zoom 88 will remain sterile unless the pouch is opened, damaged, or the “Use By” date has passed.

MATERIALS

The Zoom 88 is not made with natural rubber latex.

STORAGE AND HANDLING

Keep dry. Keep away from sunlight. Store at room temperature.

SYMBOLS GLOSSARY

Standard Reference: ISO 15223-1 §5.1.5 Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements

Symbol	Definition
	Manufacturer
	Lot number
	Use by
	Attention - See instructions for use for safety information and symbols glossary

INSTRUCTIONS FOR USE

Zoom™ 88
LARGE DISTAL PLATFORM

Imperative™
CARE

	Catalogue number
	Sterilized by ethylene oxide
	Nonpyrogenic
	Prescription only – U.S. Federal Law restricts this device to use by or on the order of a physician
	Do not use if packaging is damaged
	Do not resterilize
	Do not reuse
	Contents (numeral indicates quantity of systems in package)
	Keep away from sunlight
	Keep dry

WARRANTY

Imperative Care, Inc. (“Imperative Care”) warrants that reasonable care has been used in the design and manufacture of this device. This warranty is in lieu of and excludes all other warranties not expressly set forth herein, whether expressed or implied by operation of law or otherwise, including, but not limited to, any implied warranties of merchantability or fitness for a particular use. Handling, storage, cleaning, and sterilization of this device as well as other factors relating to the patient, diagnosis, treatment, surgical procedures, and other matters beyond Imperative Care’s control directly affect the device and the results obtained from its use. Imperative Care’s obligation under this warranty is limited to the replacement of this device and Imperative Care shall not be liable for any incidental, consequential, or special loss, damage, or expense directly or indirectly arising from the use of this device. Imperative Care neither assumes, nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with this device. This warranty is valid only if the device is used in accordance with the manufacturer’s instructions, and the warranty is limited to the original user. Any sale or other transfer or use of the device covered by this warranty to or by a user other than the original user shall cause this warranty to terminate immediately. Imperative Care assumes no liability with respect to devices reused, reprocessed, or resterilized, or serviced, repaired or modified by any party.

INSTRUCTIONS FOR USE

Zoom™ 88
LARGE DISTAL PLATFORM

Imperative™
CARE

other than the original manufacturer, and makes no warranties, expressed or implied, including but not limited to merchantability or fitness for intended use, with respect to such devices.



IMPERATIVE CARE, INC.
1359 Dell Avenue
Campbell CA 95008 U.S.A.
+1.408.502.7548

© 2020 Imperative Care, Inc., All Rights Reserved

Records processed under FOIA Request 2023-10349; Released by CDRH on 09-19-2024

Imperative
CARE

TracStar LDP™
LARGE DISTAL PLATFORM

1 **TRX™ Tip**

14cm Hydrophilic Coating Length

Ø 8F (.110 in/2.79 mm)

80 cm

Ø 6F (.088 in/2.24mm)

1 **RTV**

REF ICAC068080

LOT 000000

2018-08-15


(01) 0 082212 0001 3 (17) 183015 (10) 000000

STERILE     

 Attention - See instructions for use for safety information and symbols glossary

Rx Only Prescription only. U.S. Federal Law restricts this device to use by or on the order of a physician.

REF ICAC068090 **LOT** 000000


(01) 0 082212 0001 3 (17) 183015 (10) 000000
Imperative Care, Inc. TracStar™ 8F 908 LDP, 80 cm

REF ICAC068090 **LOT** 000000


(01) 0 082212 0001 3 (17) 183015 (10) 000000
Imperative Care, Inc. TracStar™ 6F 588 LDP, 80 cm

REF ICAC068080 **LOT** 000000


(01) 0 082212 0001 3 (17) 183015 (10) 000000
Imperative Care, Inc. TracStar™ 6F 588 LDP, 80 cm


IMPERATIVE CARE, INC.
1359 Dell Avenue
Campbell CA 95008 U.S.A.
+1 408 502 7548
© 2018 Imperative Care, Inc., All Rights Reserved. F020541-01
L01002031-01 A

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

Records processed under FOIA Request 2023-10349; Released by CDRH on 09-19-2024

Imperative
CARE

TracStar LDP™
LARGE DISTAL PLATFORM

14cm Hydrophilic Coating Length

Ø 8F (11.0 in/2.79 mm)

90 cm

Ø 6F (.088 in/2.24mm)

TRX Tip

PIN

REF ICAC088080

LOT 000000

2018-08-15

0110081221203032011719081511000000

STERILE

Attention - See instructions for use for safety information and symbols glossary

Rx Only Prescription only - U.S. Federal Law restricts this device to use by or on the order of a physician

REF ICAC088080 **LOT** 000000

0110081221203032011719081511000000

Imperative Care, Inc. TracStar® 6F D8 LDP 90 cm

REF ICAC088080 **LOT** 000000

0110081221203032011719081511000000

Imperative Care, Inc. TracStar® 6F D8 LDP 90 cm

REF ICAC088080 **LOT** 000000

0110081221203032011719081511000000

Imperative Care, Inc. TracStar® 6F D8 LDP 90 cm

IMPERATIVE CARE, INC.
1359 Dell Avenue
Campbell CA 95008 U.S.A.
+1 408 502 7548
© 2018 Imperative Care, Inc. All Rights Reserved

FG00541-02
L8L022001-02.A

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

Records processed under FOIA Request 2023-10349; Released by CDRH on 09-19-2024

Imperative
CARE

TracStar LDP™
LARGE DISTAL PLATFORM

TRX™ Tip

14cm
Hydrophilic Coating Length

Ø 8F
(.110 in/2.79 mm)

95 cm

Ø 6F (.088 in/2.24mm)

1
PIN

REF ICAC08B095

LOT 000000

2018-08-15

0910 0 0612212 00033 7 (17) 180815 (10) 000000

STERILE     

 Attention - See Instructions for use for safety information and symbols glossary

Rx Only Prescription only - U.S. Federal Law restricts this device to use by or on the order of a physician

REF ICAC08B095 **LOT** 000000

0910 0 0612212 00033 7 (17) 180815 (10) 000000

Imperative Care, Inc. TracStar™ 8F-08B-LDP, 95 cm

REF ICAC08B095 **LOT** 000000

0910 0 0612212 00033 7 (17) 180815 (10) 000000

Imperative Care, Inc. TracStar™ 8F-08B-LDP, 95 cm

REF ICAC08B095 **LOT** 000000

0910 0 0612212 00033 7 (17) 180815 (10) 000000

Imperative Care, Inc. TracStar™ 8F-08B-LDP, 95 cm

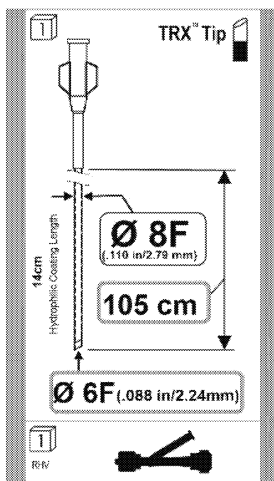


IMPERATIVE CARE, INC.
1959 Dell Avenue
Campbell CA 95008 U.S.A.
+1 408.502.7548

FIG0054-05
© 2021 Imperative Care, Inc. All Rights Reserved. LBL000001-03 A

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

Records processed under FOIA Request 2023-10349; Released by CDRH on 09-19-2024

Imperative
CARE**TracStar LDP™**
LARGE DISTAL PLATFORM**REF** ICAC088105**LOT** 000000

2018-08-15



(01) 0 0512212 03034 4 (17) 180815 (15) 000000

STERILE 

Attention - See instructions for use for safety information and symbols glossary

Rx Only Prescription only - U.S. Federal law restricts this device to use by or on the order of a physician**REF** ICAC088105 **LOT** 000000

(01) 0 0512212 03034 4 (17) 180815 (15) 000000

Imperative Care, Inc. TracStar™ 8F 105 LDP, 105 cm

REF ICAC088105 **LOT** 000000

(01) 0 0512212 03034 4 (17) 180815 (15) 000000

Imperative Care, Inc. TracStar™ 8F 105 LDP, 105 cm

REF ICAC088105 **LOT** 000000

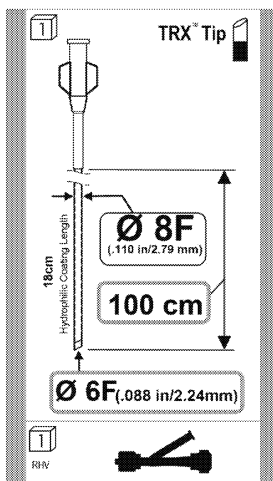
(01) 0 0512212 03034 4 (17) 180815 (15) 000000

Imperative Care, Inc. TracStar™ 8F 105 LDP, 105 cm



IMPERATIVE CARE, INC.
1359 Dell Avenue
Campbell CA 95008 U.S.A.
+1 408 502 7349
F000541-04
© 2021 Imperative Care, Inc. All Rights Reserved. LBU000001-04-A

Records processed under FOIA Request 2023-10349; Released by CDRH on 09-19-2024

Imperative
CARE**Zoom™ 88**
LARGE DISTAL PLATFORM**REF** ICTC088100**LOT** 000000

2018-08-15



(P1) 0 0512212 03035 1 (17) 180815 (19) 000000

STERILE 

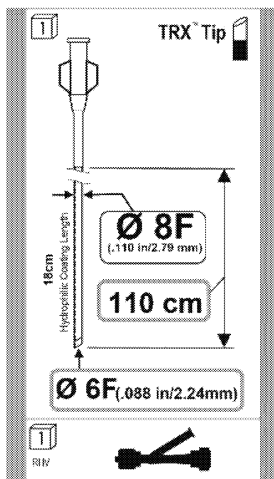
Attention - See instructions for use for safety information and symbols glossary

R_x Only Prescription only - U.S. Federal Law restricts this device to use by or on the order of a physician.

IMPERATIVE CARE, INC.
1359 Dell Avenue
Campbell CA 95008 U.S.A.
+1 408 502 7348
© 2021 Imperative Care, Inc. All Rights Reserved

FG00554-01
LB1002000-01 A

Records processed under FOIA Request 2023-10349; Released by CDRH on 09-19-2024

Imperative
CARE**Zoom™ 88**
LARGE DISTAL PLATFORM**REF** ICTC088110**LOT** 000000 2018-08-15

(01) 0 2812712 03086 8 (11) 30818 (10) 000000

STERILE**Attention** See instructions for use for safety information and symbols glossary**Rx Only** Prescription only - U.S. Federal Law restricts this device to use by or on the order of a physician**REF** ICTC088110 **LOT** 000000

(01) 0 2812712 03086 8 (11) 30818 (10) 000000

Imperative Care, Inc. ZOOM™ 88 8F 088 LDP, 110 cm

REF ICTC088110 **LOT** 000000

(01) 0 2812712 03086 8 (11) 30818 (10) 000000

Imperative Care, Inc. ZOOM™ 88 6F 088 LDP, 110 cm

REF ICTC088110 **LOT** 000000

(01) 0 2812712 03086 8 (11) 30818 (10) 000000

Imperative Care, Inc. ZOOM™ 88 5F 088 LDP, 110 cm

IMPERATIVE CARE, INC.
1359 Dell Avenue
Campbell, CA 95008 U.S.A.
+1 408.502.7548

© 2018 Imperative Care, Inc., All Rights Reserved

FD00054-02
L8L002000-03 A

Records processed under FOIA Request 2023-10349; Released by CDRH on 09-19-2024

(b)(4)

Dear Ms. Ellis,

Our goal is to complete review of the response within 30 days of receipt, which shows to be October 2, 2021, in our document tracking system.

Regards,

Leigh Anderson
Biomedical Engineer
Neurointerventional Devices Team
DHT5A: Division of Neurosurgical, Neurointerventional and Neurodiagnostic Devices
OHT5: Office of Neurological and Physical Medicine Devices
Office of Product Evaluation and Quality
CDRH | Food and Drug Administration
White Oak, Bldg. 66, Rm. 4276 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-5613
leigh.anderson@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?ID=1712&S=E>

THIS MESSAGE IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review, disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify the sender by e-mail or phone.

From: Kristin Ellis <kellis@imperativecare.com>
Sent: Tuesday, September 14, 2021 12:45 PM
To: Anderson, Leigh <Leigh.Anderson@fda.hhs.gov>
Cc: Nora Hadding <nhadding@imperativecare.com>; K212224@docs.fda.gov
Subject: RE: [EXTERNAL] K212224 Review Status

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Dear Ms. Anderson,

Thank you for the correction of the review clock day. Can you please provide me with the submission timing review goal for this Special 510(k)? This would be helpful for our planning purposes.

Kind regards,

Kristin Ellis
Regulatory Affairs Manager



M: +1.408.857.0934
E: kellis@imperativecare.com
imperativecare.com | [LinkedIn](#) | [Twitter](#) | [YouTube](#)

1359 Dell Avenue, Campbell, CA 95008
www.imperativecare.com

From: Anderson, Leigh <Leigh.Anderson@fda.hhs.gov>
Sent: Tuesday, September 14, 2021 9:22 AM
To: Kristin Ellis <kellis@imperativecare.com>
Cc: Nora Hadding <nhadding@imperativecare.com>; K212224@docs.fda.gov
Subject: RE: [EXTERNAL] K212224 Review Status

Dear Ms. Ellis,

Thank you for your email.

Our review tracking system indicates that today is day 31 of FDA's review clock for K212224. The submission is still under review at this time. If we have additional questions, we will reach out as soon as possible.

Regards,

Leigh Anderson
Biomedical Engineer
Neurointerventional Devices Team
DHT5A: Division of Neurosurgical, Neurointerventional and Neurodiagnostic Devices
OHT5: Office of Neurological and Physical Medicine Devices
Office of Product Evaluation and Quality
CDRH | Food and Drug Administration
White Oak, Bldg. 66, Rm. 4276 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-5613
leigh.anderson@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?ID=1712&S=E>

THIS MESSAGE IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review, disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify the sender by e-mail or phone.

From: Kristin Ellis <kellis@imperativecare.com>
Sent: Tuesday, September 14, 2021 11:48 AM
To: Anderson, Leigh <Leigh.Anderson@fda.hhs.gov>
Cc: Nora Hadding <nhadding@imperativecare.com>
Subject: [EXTERNAL] K212224 Review Status

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Good morning Ms. Anderson,

I hope this email finds you well. I am contacting you with regards to the review status of K212224. With the request for additional information hold and the Labor Day holiday, I am unsure of the review clock day count. I believe the clock is currently at Day 32. Can you please confirm if this is correct or if not, what date is the end of the review cycle?

Additionally, please let me know if there is any further information you require to complete the review.

Kind regards,

Kristin Ellis
Regulatory Affairs Manager



M: +1.408.857.0934
E: kellis@imperativecare.com
imperativecare.com | [LinkedIn](#) | [Twitter](#) | [YouTube](#)

1359 Dell Avenue, Campbell, CA 95008
www.imperativecare.com

Dear Ms. Ellis,

Thank you for your email reply and confirmation with the (b)(4)

Regards,

Leigh Anderson
Biomedical Engineer
Neurointerventional Devices Team
DHT5A: Division of Neurosurgical, Neurointerventional and Neurodiagnostic Devices
OHT5: Office of Neurological and Physical Medicine Devices
Office of Product Evaluation and Quality
CDRH | Food and Drug Administration
White Oak, Bldg. 66, Rm. 4276 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-5613
leigh.anderson@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?ID=1712&S=E>

THIS MESSAGE IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review, disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify the sender by e-mail or phone.

From: Kristin Ellis <kellis@imperativecare.com>
Sent: Monday, September 20, 2021 11:20 AM
To: Anderson, Leigh <Leigh.Anderson@fda.hhs.gov>
Cc: K212224@docs.fda.gov; Nora Hadding <nadding@imperativecare.com>
Subject: [EXTERNAL] RE: K212224 (b)(4)

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Good morning Ms. Anderson,

(b)(4)

Kind regards,

Kristin Ellis
Regulatory Affairs Manager



M: +1.408.857.0934
E: kellis@imperativecare.com
imperativecare.com | LinkedIn | Twitter | YouTube
1359 Dell Avenue, Campbell, CA 95008
www.imperativecare.com

From: Anderson, Leigh <Leigh.Anderson@fda.hhs.gov>
Sent: Monday, September 20, 2021 7:05 AM
To: Kristin Ellis <kellis@imperativecare.com>
Cc: K212224@docs.fda.gov
Subject: K212224 (b)(4)

Dear Ms. Ellis,

(b)(4)

Regards,

Leigh Anderson
Biomedical Engineer
Neurointerventional Devices Team
DHT5A: Division of Neurosurgical, Neurointerventional and Neurodiagnostic Devices
OHT5: Office of Neurological and Physical Medicine Devices
Office of Product Evaluation and Quality
CDRH | Food and Drug Administration
White Oak, Bldg. 66, Rm. 4276 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-5613
leigh.anderson@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?ID=1712&S=E>

THIS MESSAGE IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review, disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify the sender by e-mail or phone.

Records processed under FOIA Request 2023-10349; Released by CDRH on 09-19-2024

(b)(4)

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

From: Stephens, Nicholas * [Nicholas.Stephens@fda.hhs.gov]
Sent: 9/2/2021 5:51:32 PM
To: 'kellis@imperativecare.com' [kellis@imperativecare.com]
Subject: K212224/S001 Acknowledgement Notification
Attachments: K212224.S001- Letter.pdf



U.S. FOOD & DRUG
ADMINISTRATION

Records processed under FOIA Request 2023-10349; Released by CDRH on 09-19-2024

Acknowledgment Letter

9/2/2021

Kristin Ellis, Regulatory Affairs Manager
Imperative Care Inc.
1359 Dell Avenue
Campbell, CA 95008
UNITED STATES

Dear Kristin Ellis:

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 address listed below. Failure to do so may result in processing delays. If you believe the information identified below is incorrect, please contact the Office of Product Evaluation and Quality (OPEQ) submission support at (301) 796-5640 or OPEQSubmissionSupport@fda.hhs.gov.

Submission Number: K212224/S001

Received: 9/2/2021

Applicant: Imperative Care Inc.

Device: TracStar Large Distal Platform (LDP) Catheter, Zoom 88 Large Distal Platform (LDP) Catheter

We will notify you when the review of this document 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

Dear Ms. Anderson,

Thank you for your response and explanation, this is very helpful.

Kind regards,

Kristin Ellis

Regulatory Affairs Manager

[cid:image001.png@01D7ADF8.987F8E70]

M: +1.408.857.0934

E: kellis@imperativecare.com<<mailto:kellis@imperativecare.com>>

[imperativecare.com](http://www.imperativecare.com/)<<http://www.imperativecare.com/>> |

LinkedIn<<https://www.linkedin.com/company/imperativecare/>> |

Twitter<https://twitter.com/imperative_care> |

YouTube<<https://www.youtube.com/channel/UCOXtDHTSq28ZgSHkgtwPhyA>>

1359 Dell Avenue, Campbell, CA 95008

www.imperativecare.com<<http://www.imperativecare.com/>>

From: Anderson, Leigh <Leigh.Anderson@fda.hhs.gov>

Sent: Friday, September 17, 2021 11:06 AM

To: Kristin Ellis <kellis@imperativecare.com>

Cc: Nora Hadding <nhadding@imperativecare.com>; K212224@docs.fda.gov

Subject: RE: [EXTERNAL] K212224 Review Status

Dear Ms. Ellis,

Thanks for your email.

You are correct that the Special 510(k) guidance document notes that FDA generally intends to review Special 510(k) submissions within 30 days of receipt. However, we have not been able to complete our review by FDA day 30 for K212224, as the submission is on day 34 of FDA review today.

Just to clarify, the FDA review clock did not reset to 0 after the Additional Information (AINN) response was received, but continued counting from the day of the AINN request (day 19) for K212224. We intend to complete our review within 30 days of receipt of the response, or by October 2, 2021, for K212224 (which would be day 49). It is certainly possible we complete our review sooner than that date, but I cannot confirm a specific date for our review decision. I don't think the potential for the review to take up to an additional 30 days upon receipt of the AINN response is described in any specific document or webpage.

Regards,

Leigh Anderson

Biomedical Engineer

Neurointerventional Devices Team

DHT5A: Division of Neurosurgical, Neurointerventional and Neurodiagnostic Devices

OHT5: Office of Neurological and Physical Medicine Devices

Office of Product Evaluation and Quality

CDRH | Food and Drug Administration

White Oak, Bldg. 66, Rm. 4276 | 10903 New Hampshire Avenue | Silver Spring, MD 20993

Ph: 301-796-5613

leigh.anderson@fda.hhs.gov<mailto:leigh.anderson@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?ID=1712&S=E<https://nam12.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.research.net%2Fs%2Fcdrhcustomerservice%3FID%3D1712%26S%3DE&data=04%7C01%7Ckellis%40imperativecare.com%7Caf3dddc33414f3e5d7408d97a05de17%7Cf9bc67a2b9bd4bcc974aec60ef533fdc%7C0%7C0%7C637674987902025444%7CUnknown%7CTWFpbGZsb3d8eyJWIoImc4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6IklhaWwiLCJXVCI6Mn0%3D%7C1000&sdata=eYKiTemLLLQW0yqlSte89kJtbCpEpwkr%2FB4feWoVRJU%3D&reserved=0>>

THIS MESSAGE IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review, disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify the sender by e-mail or phone.

From: Kristin Ellis <kellis@imperativecare.com<mailto:kellis@imperativecare.com>>

Sent: Friday, September 17, 2021 10:51 AM

To: Anderson, Leigh <Leigh.Anderson@fda.hhs.gov<mailto:Leigh.Anderson@fda.hhs.gov>>

Cc: Nora Hadding <nhadding@imperativecare.com<mailto:nhadding@imperativecare.com>>; K212224@docs.fda.gov<mailto:K212224@docs.fda.gov>

Subject: RE: [EXTERNAL] K212224 Review Status

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Good morning Ms. Anderson,

I know you must be very busy but I'm hoping that you can help me to better understand the review process for Special 510(k)s and the impact to the review time with issuance of an Additional Information letter. I reviewed the FDA Guidance Document "FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Goals, Guidance for Industry and Food and Drug Administration Staff" issued on October 2, 2017 and was not able to locate any language which indicates a reset of the review clock to 30 days for Special 510(k)s. The guidance document indicates that the clock stops upon issuance of a request for additional information and starts again upon receipt of the information. Following this guidance, I was under the impression that the review clock would have started back up at day 20 when Document Control received the requested additional information. Any help you can provide in indicating where I missed this information is appreciated for future submissions so that I can correctly advise project teams.

In addition, is it possible that we will be receiving a response sooner than Oct.2? As always, please let me know if there is any additional information we can provide for the review.

I appreciate the time you have already spent reviewing K212224 and answering my earlier

questions. Thank you in advance for taking the time to address these additional questions for my understanding.

Kind regards,

Kristin Ellis

Kristin Ellis

Regulatory Affairs Manager

[cid:image001.png@01D7ADF8.987F8E70]

M: +1.408.857.0934

E: kellis@imperativecare.com<<mailto:kellis@imperativecare.com>>

<http://www.imperativecare.com/> |
LinkedIn<<https://nam12.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.linkedin.com%2Fcompany%2Fimperativecare%2F&data=04%7C01%7Ckellis%40imperativecare.com%7Caf3dddc33414f3e5d7408d97a05de17%7Cf9bc67a2b9bd4bcc974aec60ef533fdc%7C0%7C0%7C637674987902035403%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6IklhaWwiLCJXVCi6Mn0%3D%7C1000&sdata=h3UC0Ovz9M3BkNHTwrW6dz4ymyKbqjITuWggWoDECrg%3D&reserved=0>> |
Twitter<https://nam12.safelinks.protection.outlook.com/?url=https%3A%2F%2Ftwitter.com%2Fimperative_care&data=04%7C01%7Ckellis%40imperativecare.com%7Caf3dddc33414f3e5d7408d97a05de17%7Cf9bc67a2b9bd4bcc974aec60ef533fdc%7C0%7C0%7C637674987902035403%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6IklhaWwiLCJXVCi6Mn0%3D%7C1000&sdata=YsXMo13ZjqA5JFC2jz8gJbhmR5cezEyU%2FUQ%2B%2FQBWzaU%3D&reserved=0> |
YouTube<<https://www.youtube.com/channel/UCOXtDHTSq28ZgSHkgtwPhyA>>

1359 Dell Avenue, Campbell, CA 95008

www.imperativecare.com<<http://www.imperativecare.com/>>

From: Anderson, Leigh <Leigh.Anderson@fda.hhs.gov<<mailto:Leigh.Anderson@fda.hhs.gov>>>

Sent: Tuesday, September 14, 2021 1:49 PM

To: Kristin Ellis <kellis@imperativecare.com<<mailto:kellis@imperativecare.com>>>

Cc: Nora Hadding <nhadding@imperativecare.com<<mailto:nhadding@imperativecare.com>>>;
K212224@docs.fda.gov<<mailto:K212224@docs.fda.gov>>

Subject: RE: [EXTERNAL] K212224 Review Status

Dear Ms. Ellis,

Our goal is to complete review of the response within 30 days of receipt, which shows to be October 2, 2021, in our document tracking system.

Regards,

Leigh Anderson

Biomedical Engineer

Neurointerventional Devices Team

DHT5A: Division of Neurosurgical, Neurointerventional and Neurodiagnostic Devices

OHT5: Office of Neurological and Physical Medicine Devices

Office of Product Evaluation and Quality

CDRH | Food and Drug Administration

White Oak, Bldg. 66, Rm. 4276 | 10903 New Hampshire Avenue | Silver Spring, MD 20993

Ph: 301-796-5613

leigh.anderson@fda.hhs.gov<mailto:leigh.anderson@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?ID=1712&S=E<https://nam12.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.research.net%2Fs%2Fcdrhcustomerservice%3FID%3D1712%26S%3DE&data=04%7C01%7Ckellis%40imperativecare.com%7Caf3dddc33414f3e5d7408d97a05de17%7Cf9bc67a2b9bd4bcc974aec60ef533fdc%7C0%7C0%7C637674987902045354%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6IklhaWwiLCJXVCi6Mn0%3D%7C1000&sdata=sVJQT9todXlpaGG%2FpQSdtmQ5cKsKRk%2F484zsipeyR%2FM%3D&reserved=0>>

THIS MESSAGE IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review, disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify the sender by e-mail or phone.

From: Kristin Ellis <kellis@imperativecare.com<mailto:kellis@imperativecare.com>>

Sent: Tuesday, September 14, 2021 12:45 PM

To: Anderson, Leigh <Leigh.Anderson@fda.hhs.gov<mailto:Leigh.Anderson@fda.hhs.gov>>

Cc: Nora Hadding <nhadding@imperativecare.com<mailto:nhadding@imperativecare.com>>; K212224@docs.fda.gov<mailto:K212224@docs.fda.gov>

Subject: RE: [EXTERNAL] K212224 Review Status

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Dear Ms. Anderson,

Thank you for the correction of the review clock day. Can you please provide me with the submission timing review goal for this Special 510(k)? This would be helpful for our planning purposes.

Kind regards,

Kristin Ellis

Regulatory Affairs Manager

[cid:image001.png@01D7ADF8.987F8E70]

M: +1.408.857.0934

E: kellis@imperativecare.com<mailto:kellis@imperativecare.com>

imperativecare.com<http://www.imperativecare.com/> | LinkedIn<https://nam12.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.linkedin.com%2Fcompany%2Fimperativecare%2F&data=04%7C01%7Ckellis%40imperativecare.com%7Caf3dddc33414f3e5d7408d97a05de17%7Cf9bc67a2b9bd4bcc974aec60ef533fdc%7C0%7C0%7C637674987902045354%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6IklhaWwiLCJXVCi6Mn0%3D%7C1000&sdata=JAFu8xYTQQc5JmCF2rrjK%2F0%2BBUMtFBRe%2BTaIRJEYQMc%3D&reserved=0> |

Twitter<https://nam12.safelinks.protection.outlook.com/?url=https%3A%2F%2Ftwitter.com%2Fimperative_care&data=04%7C01%7Ckellis%40imperativecare.com%7Caf3dddc33414f3e5d7408d97a05de17%7Cf9bc67a2b9bd4bcc974aec60ef533fdc%7C0%7C0%7C637674987902045354%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6IklhaWwiLCJXVCi6Mn0%3D%7C1000&sdata=LlnOMat%2Bu%2FDrxKzOYArst76RITvLNWGsfxBv0arhQpA%3D&reserved=0 |
YouTube<<https://www.youtube.com/channel/UCOXtDHTSq28ZgSHkgtwPhyA>>

1359 Dell Avenue, Campbell, CA 95008

www.imperativecare.com<<http://www.imperativecare.com/>>

From: Anderson, Leigh <Leigh.Anderson@fda.hhs.gov<<mailto:Leigh.Anderson@fda.hhs.gov>>>

Sent: Tuesday, September 14, 2021 9:22 AM

To: Kristin Ellis <kellis@imperativecare.com<<mailto:kellis@imperativecare.com>>>

Cc: Nora Hadding <nhadding@imperativecare.com<<mailto:nhadding@imperativecare.com>>>;
K212224@docs.fda.gov<<mailto:K212224@docs.fda.gov>>

Subject: RE: [EXTERNAL] K212224 Review Status

Dear Ms. Ellis,

Thank you for your email.

Our review tracking system indicates that today is day 31 of FDA's review clock for K212224. The submission is still under review at this time. If we have additional questions, we will reach out as soon as possible.

Regards,

Leigh Anderson

Biomedical Engineer

Neurointerventional Devices Team

DHT5A: Division of Neurosurgical, Neurointerventional and Neurodiagnostic Devices

OHT5: Office of Neurological and Physical Medicine Devices

Office of Product Evaluation and Quality

CDRH | Food and Drug Administration

White Oak, Bldg. 66, Rm. 4276 | 10903 New Hampshire Avenue | Silver Spring, MD 20993

Ph: 301-796-5613

leigh.anderson@fda.hhs.gov<<mailto:leigh.anderson@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?ID=1712&S=E><<https://nam12.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.research.net%2Fs%2Fcdrhcustomerservice%3FID%3D1712%26S%3DE&data=04%7C01%7Ckellis%40imperativecare.com%7Caf3dddc33414f3e5d7408d97a05de17%7Cf9bc67a2b9bd4bcc974aec60ef533fdc%7C0%7C0%7C637674987902055315%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6IklhaWwiLCJXVCi6Mn0%3D%7C1000&sdata=Hpv%2BamKH28Uzrb8qzkexiMbHA44EHZ5OY9R%2Fc8UBcF4%3D&reserved=0>>

THIS MESSAGE IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the

document to the addressee, you are hereby notified that any review, disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify the sender by e-mail or phone.

From: Kristin Ellis <kellis@imperativecare.com<mailto:kellis@imperativecare.com>>
Sent: Tuesday, September 14, 2021 11:48 AM
To: Anderson, Leigh <Leigh.Anderson@fda.hhs.gov<mailto:Leigh.Anderson@fda.hhs.gov>>
Cc: Nora Hadding <nhadding@imperativecare.com<mailto:nhadding@imperativecare.com>>
Subject: [EXTERNAL] K212224 Review Status

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Good morning Ms. Anderson,

I hope this email finds you well. I am contacting you with regards to the review status of K212224. With the request for additional information hold and the Labor Day holiday, I am unsure of the review clock day count. I believe the clock is currently at Day 32. Can you please confirm if this is correct or if not, what date is the end of the review cycle?

Additionally, please let me know if there is any further information you require to complete the review.

Kind regards,

Kristin Ellis

Regulatory Affairs Manager

[cid:image001.png@01D7ADF8.987F8E70]

M: +1.408.857.0934

E: kellis@imperativecare.com<mailto:kellis@imperativecare.com>

imperativecare.com<http://www.imperativecare.com/> |
LinkedIn<https://nam12.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.linkedin.com%2Fcompany%2Fimperativecare%2F&data=04%7C01%7Ckellis%40imperativecare.com%7Caf3dddc33414f3e5d7408d97a05de17%7Cf9bc67a2b9bd4bcc974aec60ef533fdc%7C0%7C0%7C637674987902055315%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6IklhaWwiLCJXVCi6Mn0%3D%7C1000&sdata=4kzEQAzK%2B2TABN1xwExhj99tXz8ymaUP6iKg4ExzFRM%3D&reserved=0> |
Twitter<https://nam12.safelinks.protection.outlook.com/?url=https%3A%2F%2Ftwitter.com%2Fimperative_care&data=04%7C01%7Ckellis%40imperativecare.com%7Caf3dddc33414f3e5d7408d97a05de17%7Cf9bc67a2b9bd4bcc974aec60ef533fdc%7C0%7C0%7C637674987902065268%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6IklhaWwiLCJXVCi6Mn0%3D%7C1000&sdata=vn%2F%2FAuypi6eKGg7rarTttYuXm79xi7101zMBypNfTfI%3D&reserved=0> |
YouTube<https://www.youtube.com/channel/UCOXtDHTSq28ZgSHkgtwPhyA>

1359 Dell Avenue, Campbell, CA 95008

www.imperativecare.com<http://www.imperativecare.com/>

Dear Ms. Anderson,

Thank you for your response and explanation, this is very helpful.

Kind regards,

Kristin Ellis

Regulatory Affairs Manager



M: +1.408.857.0934

E: kellis@imperativecare.com

imperativecare.com | [LinkedIn](#) | [Twitter](#) | [YouTube](#)

1359 Dell Avenue, Campbell, CA 95008

www.imperativecare.com

From: Anderson, Leigh <Leigh.Anderson@fda.hhs.gov>

Sent: Friday, September 17, 2021 11:06 AM

To: Kristin Ellis <kellis@imperativecare.com>

Cc: Nora Hadding <nhadding@imperativecare.com>; K212224@docs.fda.gov

Subject: RE: [EXTERNAL] K212224 Review Status

Dear Ms. Ellis,

Thanks for your email.

You are correct that the Special 510(k) guidance document notes that FDA generally intends to review Special 510(k) submissions within 30 days of receipt. However, we have not been able to complete our review by FDA day 30 for K212224, as the submission is on day 34 of FDA review today.

Just to clarify, the FDA review clock did not reset to 0 after the Additional Information (AINN) response was received, but continued counting from the day of the AINN request (day 19) for K212224. We intend to complete our review within 30 days of receipt of the response, or by October 2, 2021, for K212224 (which would be day 49). It is certainly possible we complete our review sooner than that date, but I cannot confirm a specific date for our review decision. I don't think the potential for the review to take up to an additional 30 days upon receipt of the AINN response is described in any specific document or webpage.

Regards,

Leigh Anderson

Biomedical Engineer

Neurointerventional Devices Team

DHT5A: Division of Neurosurgical, Neurointerventional and Neurodiagnostic Devices

OHT5: Office of Neurological and Physical Medicine Devices

Office of Product Evaluation and Quality

CDRH | Food and Drug Administration

White Oak, Bldg. 66, Rm. 4276 | 10903 New Hampshire Avenue | Silver Spring, MD 20993

Ph: 301-796-5613

leigh.anderson@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?ID=1712&S=E>

THIS MESSAGE IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review, disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify the sender by e-mail or phone.

From: Kristin Ellis <kellis@imperativecare.com>

Sent: Friday, September 17, 2021 10:51 AM

To: Anderson, Leigh <Leigh.Anderson@fda.hhs.gov>

Cc: Nora Hadding <nhadding@imperativecare.com>; K212224@docs.fda.gov

Subject: RE: [EXTERNAL] K212224 Review Status

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Good morning Ms. Anderson,

I know you must be very busy but I'm hoping that you can help me to better understand the review process for Special 510(k)s and the impact to the review

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

time with issuance of an Additional Information letter. I reviewed the FDA Guidance Document "FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Goals, Guidance for Industry and Food and Drug Administration Staff" issued on October 2, 2017 and was not able to locate any language which indicates a reset of the review clock to 30 days for Special 510(k)s. The guidance document indicates that the clock stops upon issuance of a request for additional information and starts again upon receipt of the information. Following this guidance, I was under the impression that the review clock would have started back up at day 20 when Document Control received the requested additional information. Any help you can provide in indicating where I missed this information is appreciated for future submissions so that I can correctly advise project teams.

In addition, is it possible that we will be receiving a response sooner than Oct.2? As always, please let me know if there is any additional information we can provide for the review.

I appreciate the time you have already spent reviewing K212224 and answering my earlier questions. Thank you in advance for taking the time to address these additional questions for my understanding.

Kind regards,
Kristin Ellis

Kristin Ellis
Regulatory Affairs Manager



M: +1.408.857.0934
E: kellis@imperativecare.com
imperativecare.com | [LinkedIn](#) | [Twitter](#) | [YouTube](#)

1359 Dell Avenue, Campbell, CA 95008
www.imperativecare.com

From: Anderson, Leigh <Leigh.Anderson@fda.hhs.gov>
Sent: Tuesday, September 14, 2021 1:49 PM
To: Kristin Ellis <kellis@imperativecare.com>
Cc: Nora Hadding <nhadding@imperativecare.com>; K212224@docs.fda.gov
Subject: RE: [EXTERNAL] K212224 Review Status

Dear Ms. Ellis,

Our goal is to complete review of the response within 30 days of receipt, which shows to be October 2, 2021, in our document tracking system.

Regards,

Leigh Anderson
Biomedical Engineer
Neurointerventional Devices Team
DHTSA: Division of Neurosurgical, Neurointerventional and Neurodiagnostic Devices
OHT5: Office of Neurological and Physical Medicine Devices
Office of Product Evaluation and Quality
CDRH | Food and Drug Administration
White Oak, Bldg. 66, Rm. 4276 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-5613
leigh.anderson@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?ID=1712&S=E>

THIS MESSAGE IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review, disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify the sender by e-mail or phone.

From: Kristin Ellis <kellis@imperativecare.com>
Sent: Tuesday, September 14, 2021 12:45 PM
To: Anderson, Leigh <Leigh.Anderson@fda.hhs.gov>
Cc: Nora Hadding <nhadding@imperativecare.com>; K212224@docs.fda.gov
Subject: RE: [EXTERNAL] K212224 Review Status

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Dear Ms. Anderson,

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

Thank you for the correction of the review clock day. Can you please provide me with the submission timing review goal for this Special 510(k)? This would be helpful for our planning purposes.

Kind regards,

.....
Kristin Ellis

Regulatory Affairs Manager



M: +1.408.857.0934

E: kellis@imperativecare.com

imperativecare.com | [LinkedIn](#) | [Twitter](#) | [YouTube](#)

1359 Dell Avenue, Campbell, CA 95008

www.imperativecare.com

From: Anderson, Leigh <Leigh.Anderson@fda.hhs.gov>

Sent: Tuesday, September 14, 2021 9:22 AM

To: Kristin Ellis <kellis@imperativecare.com>

Cc: Nora Hadding <nhadding@imperativecare.com>; K212224@docs.fda.gov

Subject: RE: [EXTERNAL] K212224 Review Status

Dear Ms. Ellis,

Thank you for your email.

Our review tracking system indicates that today is day 31 of FDA's review clock for K212224. The submission is still under review at this time. If we have additional questions, we will reach out as soon as possible.

Regards,

Leigh Anderson

Biomedical Engineer

Neurointerventional Devices Team

DHT5A: Division of Neurosurgical, Neurointerventional and Neurodiagnostic Devices

OHT5: Office of Neurological and Physical Medicine Devices

Office of Product Evaluation and Quality

CDRH | Food and Drug Administration

White Oak, Bldg. 66, Rm. 4276 | 10903 New Hampshire Avenue | Silver Spring, MD 20993

Ph: 301-796-5613

leigh.anderson@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?ID=1712&S=E>

THIS MESSAGE IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review, disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify the sender by e-mail or phone.

From: Kristin Ellis <kellis@imperativecare.com>

Sent: Tuesday, September 14, 2021 11:48 AM

To: Anderson, Leigh <Leigh.Anderson@fda.hhs.gov>

Cc: Nora Hadding <nhadding@imperativecare.com>

Subject: [EXTERNAL] K212224 Review Status

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Good morning Ms. Anderson,

I hope this email finds you well. I am contacting you with regards to the review status of K212224. With the request for additional information hold and the Labor Day holiday, I am unsure of the review clock day count. I believe the clock is currently at Day 32. Can you please confirm if this is correct or if not, what date is the end of the review cycle?

Additionally, please let me know if there is any further information you require to complete the review.

Kind regards,

.....
Kristin Ellis

Regulatory Affairs Manager



M: +1.408.857.0934

E: kellis@imperativecare.com

imperativecare.com | [LinkedIn](#) | [Twitter](#) | [YouTube](#)

1359 Dell Avenue, Campbell, CA 95008

www.imperativecare.com

K212224 – LDP Catheters – Responses to Interactive Request

(b)(4)

(b)(4)

FDA Request:

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

Dear Ms. Anderson,

Thank you for acknowledging the use of the corrected forms. Please let me know if you have any other questions or need further information.

Kind regards,

Kristin Ellis

Regulatory Affairs Manager

[cid:image001.png@01D7A586.2D30E9E0]

M: +1.408.857.0934

E: kellis@imperativecare.com<<mailto:kellis@imperativecare.com>>

[imperativecare.com](http://www.imperativecare.com/)<<http://www.imperativecare.com/>> |
[LinkedIn](https://www.linkedin.com/company/imperativecare/)<<https://www.linkedin.com/company/imperativecare/>> |
[Twitter](https://twitter.com/imperative_care)<https://twitter.com/imperative_care> |
[YouTube](https://www.youtube.com/channel/UCOXtDHTSq28ZgSHkgtwPhyA)<<https://www.youtube.com/channel/UCOXtDHTSq28ZgSHkgtwPhyA>>

1359 Dell Avenue, Campbell, CA 95008

www.imperativecare.com<<http://www.imperativecare.com/>>

From: Anderson, Leigh <Leigh.Anderson@fda.hhs.gov>

Sent: Thursday, September 9, 2021 2:21 PM

To: Kristin Ellis <kellis@imperativecare.com>

Cc: K212224@docs.fda.gov

Subject: RE: [EXTERNAL] RE: K212224 - Interactive Request -

(b)(4)

(b)(4)

Dear Ms. Ellis,

Thank you for your quick review and reply. We will use the latest versions I sent by email at this point moving forward.

If we have additional questions, we will reach out to you.

Regards,

Leigh Anderson

Biomedical Engineer

Neurointerventional Devices Team

DHT5A: Division of Neurosurgical, Neurointerventional and Neurodiagnostic Devices

OHT5: Office of Neurological and Physical Medicine Devices

Office of Product Evaluation and Quality

CDRH | Food and Drug Administration

White Oak, Bldg. 66, Rm. 4276 | 10903 New Hampshire Avenue | Silver Spring, MD 20993

Ph: 301-796-5613

leigh.anderson@fda.hhs.gov<<mailto:leigh.anderson@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?ID=1712&S=E&https://nam12.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.research.net%2Fs%2Fcdrhcustomerservice%3FID%3D1712%26S%3DE&data=04%7C01%7Ckellis%40imperativecare.com%7C83104d1f3b2e4748a3b508d973d7cb55%7Cf9bc67a2b9bd4bcc974aec60ef533fdc%7C0%7C0%7C637668192939450786%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6IklhaWwiLCJXVCI6Mn0%3D%7C1000&sdata=vXUZM%2FuTiUH%2Bs84Ylb%2Feodl6ENZCdLGs3gUH9cs%2F6%2FM%3D&reserved=0>

THIS MESSAGE IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review, disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify the sender by e-mail or phone.

From: Kristin Ellis <kellis@imperativecare.com<mailto:kellis@imperativecare.com>>

Sent: Thursday, September 9, 2021 5:19 PM

To: Anderson, Leigh <Leigh.Anderson@fda.hhs.gov<mailto:Leigh.Anderson@fda.hhs.gov>>

Cc: K212224@docs.fda.gov<mailto:K212224@docs.fda.gov>

Subject: [EXTERNAL] RE: K212224 - Interactive Request -

(b)(4)

(b)(4)

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Dear Ms. Anderson,

(b)(4)

Kind regards,

Kristin Ellis

Regulatory Affairs Manager

[cid:image001.png@01D7A586.2D30E9E0]

M: +1.408.857.0934

E: kellis@imperativecare.com<mailto:kellis@imperativecare.com>

imperativecare.com<http://www.imperativecare.com/> |
LinkedIn<https://nam12.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.linkedin.com%2Fcompany%2Fimperativecare%2F&data=04%7C01%7Ckellis%40imperativecare.com%7C83104d1f3b2e4748a3b508d973d7cb55%7Cf9bc67a2b9bd4bcc974aec60ef533fdc%7C0%7C0%7C637668192939460740%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6IklhaWwiLCJXVCI6Mn0%3D%7C1000&sdata=y2nhA8mcBoVPhJm5fLUZocCCxwtGigMO0bkGvqa8goY%3D&reserved=0> |
Twitter<https://nam12.safelinks.protection.outlook.com/?url=https%3A%2F%2Ftwitter.com%2Fimperative_care&data=04%7C01%7Ckellis%40imperativecare.com%7C83104d1f3b2e4748a3b508d973d7cb55%7Cf9bc67a2b9bd4bcc974aec60ef533fdc%7C0%7C0%7C637668192939460740%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6IklhaWwiLCJXVCI6Mn0%3D%7C1000&sdata=89mEzypcb1%2FE0XnVBH4ZTBzOM25oqlDNEZ4fhoWPGw%3D&reserved=0> |
YouTube<https://www.youtube.com/channel/UCOXtDHTSq28ZgSHkgtwPhyA>

1359 Dell Avenue, Campbell, CA 95008

www.imperativecare.com<<http://www.imperativecare.com/>>

From: Anderson, Leigh <Leigh.Anderson@fda.hhs.gov<mailto:Leigh.Anderson@fda.hhs.gov>>

Sent: Thursday, September 9, 2021 2:11 PM

To: Kristin Ellis <kellis@imperativecare.com<mailto:kellis@imperativecare.com>>

Cc: K212224@docs.fda.gov<mailto:K212224@docs.fda.gov>

Subject: K212224 - Interactive Request -

(b)(4)

(b)(4)

Dear Ms. Ellis,

(b)(4)

Regards,

Leigh Anderson

Biomedical Engineer

Neurointerventional Devices Team

DHT5A: Division of Neurosurgical, Neurointerventional and Neurodiagnostic Devices

OHT5: Office of Neurological and Physical Medicine Devices

Office of Product Evaluation and Quality

CDRH | Food and Drug Administration

White Oak, Bldg. 66, Rm. 4276 | 10903 New Hampshire Avenue | Silver Spring, MD 20993

Ph: 301-796-5613

leigh.anderson@fda.hhs.gov<mailto:leigh.anderson@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?ID=1712&S=E<https://nam12.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.research.net%2Fs%2Fcdrhcustomerservice%3FID%3D1712%26S%3DE&data=04%7C01%7Ckellis%40imperativecare.com%7C83104d1f3b2e4748a3b508d973d7cb55%7Cf9bc67a2b9bd4bcc974aec60ef533fdc%7C0%7C0%7C637668192939460740%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6IklhaWwiLCJXVCI6Mn0%3D%7C1000&sdata=QxUq6Dz5IOQa3GBtHr7X706hRc1bO56g7EOMfnD%2FHwY%3D&reserved=0>>

THIS MESSAGE IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review, disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify the sender by e-mail or phone.

Dear Ms. Ellis,

Thank you for providing an interactive response with (b)(4) I confirm receipt.

Regards,

Leigh Anderson
Biomedical Engineer
Neurointerventional Devices Team
DHT5A: Division of Neurosurgical, Neurointerventional and Neurodiagnostic Devices
OHT5: Office of Neurological and Physical Medicine Devices
Office of Product Evaluation and Quality
CDRH | Food and Drug Administration
White Oak, Bldg. 66, Rm. 4276 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-5613
leigh.anderson@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?ID=1712&S=E>

THIS MESSAGE IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review, disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify the sender by e-mail or phone.

From: Kristin Ellis <kellis@imperativecare.com>
Sent: Saturday, July 24, 2021 9:37 PM
To: Anderson, Leigh <Leigh.Anderson@fda.hhs.gov>
Cc: K212224@docs.fda.gov; Nora Hadding <nadding@imperativecare.com>
Subject: [EXTERNAL] RE: K212224 - Interactive Request - (b)(4) (Please Reply by Mon Jul 26)

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Dear Ms. Anderson,

Attached please find the response to FDA's Interactive Request for the (b)(4) Please let me know if you have further questions or need any further clarification.

Kind regards,

Kristin Ellis
Regulatory Affairs Manager



M: +1.408.857.0934
E: kellis@imperativecare.com
imperativecare.com | [LinkedIn](#) | [Twitter](#) | [YouTube](#)

1359 Dell Avenue, Campbell, CA 95008
www.imperativecare.com

From: Anderson, Leigh <Leigh.Anderson@fda.hhs.gov>
Sent: Friday, July 23, 2021 7:38 AM
To: Kristin Ellis <kellis@imperativecare.com>
Cc: K212224@docs.fda.gov
Subject: K212224 - Interactive Request - (b)(4) (Please Reply by Mon Jul 26)

Dear Ms. Ellis,

I am lead reviewer for K212224 for the TracStar and Zoom 88 Large Distal Platform Catheters. We are still early in our review and primarily in the administrative RTA review phase. We have noticed that the following (b)(4)

We request that you provide a response to the following items via email by Monday, July 26 to facilitate our review. If you have concerns with the proposed timeline, please let me know.

FDA Request:

(b)(4)

Regards,

Leigh Anderson
Biomedical Engineer
Neurointerventional Devices Team
DHT5A: Division of Neurosurgical, Neurointerventional and Neurodiagnostic Devices
OHT5: Office of Neurological and Physical Medicine Devices
Office of Product Evaluation and Quality
CDRH | Food and Drug Administration
White Oak, Bldg. 66, Rm. 4276 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-5613
leigh.anderson@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?ID=1712&S=E>

THIS MESSAGE IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review, disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify the sender by e-mail or phone.

Dear Ms. Ellis,

Thank you for your email and update regarding K212224.

Regards,

Leigh Anderson
Biomedical Engineer
Neurointerventional Devices Team
DHT5A: Division of Neurosurgical, Neurointerventional and Neurodiagnostic Devices
OHT5: Office of Neurological and Physical Medicine Devices
Office of Product Evaluation and Quality
CDRH | Food and Drug Administration
White Oak, Bldg. 66, Rm. 4276 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-5613
leigh.anderson@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?ID=1712&S=E>

THIS MESSAGE IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review, disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify the sender by e-mail or phone.

From: Kristin Ellis <kellis@imperativecare.com>
Sent: Monday, August 30, 2021 1:24 PM
To: Anderson, Leigh <Leigh.Anderson@fda.hhs.gov>
Subject: [EXTERNAL] RE: K212224 is on Hold Pending Your Response

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Good afternoon Ms. Anderson,

I apologize for not responding sooner, I acknowledge the receipt of the request for additional information. It is my intention to provide a response to you this week.

Kind regards,

Kristin Ellis
Regulatory Affairs Manager



M: +1.408.857.0934
E: kellis@imperativecare.com
imperativecare.com | [LinkedIn](#) | [Twitter](#) | [YouTube](#)

1359 Dell Avenue, Campbell, CA 95008
www.imperativecare.com

From: Leigh Anderson [LEIGH.ANDERSON] <leigh.anderson@fda.hhs.gov>
Sent: Wednesday, August 4, 2021 12:45 PM
To: Kristin Ellis <kellis@imperativecare.com>
Cc: Leigh Anderson [LEIGH.ANDERSON] <leigh.anderson@fda.hhs.gov>
Subject: K212224 is on Hold Pending Your Response

August 4, 2021

We have reviewed your submission. Please see attached.

If you have any questions, please contact the lead reviewer assigned to your submission, Leigh Anderson.

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

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

July 28, 2021</br></br>

Acceptance Review Notification - Accepted

<p>An administrative acceptance review was conducted on your submission K212224, 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.</p>

<p>The lead reviewer assigned to your submission is me, Leigh Anderson. The file is being reviewed in Office of Health Technology 5, Division of Health Technology 5 A. The first line supervisor is the Assistant Director, Neurointerventional Devices. You may contact me at any point during the review if you have questions or concerns. You can provide valuable support for CDRH to continue to improve our programs by raising to the attention of management relevant issues that arise during the course of this review. If you feel there is an unresolved issue or a matter that requires additional attention, you should contact the Assistant Director. If your concern or issue is not addressed by the Assistant Director, you should contact the Division Director or OHT Director. The contact information for each management level can be found in the CDRH Management Directory.</p>

<p>We will contact you should we require any additional information during the course of the substantive review. FDA aims to apply the least burdensome principles when requesting additional information. </p>

<p>If you have general questions about the review process for your submission, you should contact OPEQSubmissionSupport@fda.hhs.gov.</p>

<p>*** This is a system-generated email notification ***</p>

510(k) Summary

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

510(k) Summary

A. Submitter Information

Submitter's Name: Imperative Care, Inc.
Address: 1359 Dell Avenue
Campbell, CA 95008
Contact Person: Kristin Ellis
Telephone: 408-857-0934
Email: kellis@imperativecare.com
Date of Preparation: September 1, 2021

B. Subject Device

Proprietary Names: TracStar™ LDP Large Distal Platform
Zoom™ 88 Large Distal Platform
Common/Usual Name: Guide Catheter
Classification Name: Catheter, Percutaneous, Neurovasculature
Product Code: QJP
DQY
Regulation: 21 CFR 870.1250

C. Predicate Device(s)

Proprietary Name: TracStar™ Large Distal Platform
ZOOM™ 88 Large Distal Platform
ZOOM™ 88-T Large Distal Platform
Common/Usual Name: Guide Catheter
Classification Name: Catheter, Percutaneous, Neurovasculature
Product Code: QJP, DQY
Regulation: 21 CFR. 870.1250
Manufacturer: Imperative Care, Inc.
510(k): K203764

Proprietary Name: EagleRay Long Sheath
EagleRay Access Catheter
Common/Usual Name: Guide Catheter
Classification Name: Catheter, Percutaneous
Product Code: DQY
Regulation: 21 CFR. 870.1250
Manufacturer: Imperative Care Inc.
510(k): K180169

D. Device Description:

The Imperative Care Large Distal Platform (LDP) Catheters include the TracStar™ LDP Large Distal Platform and Zoom™ 88 Large Distal Platform. The LDP Catheters are 0.038" diameter or smaller guidewire compatible single lumen guide catheters that provide

access to peripheral, coronary and neuro vasculature. The catheters are comprised of a hollow cylindrical tube bonded at the proximal end to a standard luer fitting. The wall of the tube is constructed using a combination of metal coils/braids and medical grade polymers. The distal section of each catheter has a hydrophilic coating to enhance tracking through tortuous vasculature. An angled distal soft tip facilitates smooth tracking past vessel branches. A radiopaque marker provides visual confirmation of the distal tip location under fluoroscopy. LDP Catheters have an inner diameter of 0.088" (6F compatible), and a maximum outer diameter of 0.110". The LDP guide catheters are packaged with a rotating hemostasis valve (RHV) that is attached to the proximal luer to help maintain hemostasis.

Accessory devices required, but not supplied include:

- Guidewires
- Support/diagnostic catheters
- Introducer sheaths

E. Indications for Use:

The TracStar LDP Large Distal Platform is indicated for the introduction of interventional devices into the peripheral, coronary, and neuro vasculature.

The Zoom 88 Large Distal Platform is indicated for the introduction of interventional devices into the peripheral, coronary, and neuro vasculature.

F. Principles of Operation:

The LDP Catheters may be used with support catheters to assist in accessing the target vasculature. During use, the male luer of the RHV is attached to the proximal luer of the LDP Catheter to create a continuous lumen through the catheter and to the RHV ports. The female luer is typically connected to a saline drip line while the LDP Catheter is advanced through the vasculature. Use of the LDP Catheter relies on standard percutaneous interventional techniques, including access site preparation, introducing the catheter portion of the device, advancing the catheter under fluoroscopy, withdrawing the catheter, and closing the access site.

G. Predicate Comparison:

The predicate devices are the Imperative Care LDP Catheters cleared under K203764 and K180169. The predicate and subject devices share the same intended use, basic technological characteristics, and the same performance characteristics, demonstrated through bench and

laboratory testing as shown in **Table 1**. Modifications include dimensional updates, additional axial and radial reinforcements, and manufacturing process improvements.

Table 1: Comparison of Subject and Predicate Devices

Device Attribute	Subject device	Predicate devices	
FDA Product Classification	Class II, QJP and DQY, 21 CFR 870.1250	Class II, QJP and DQY, 21 CFR 870.1250	Class II, DQY, 21 CFR 870.1250
Product Name	TracStar LDP Large Distal Platform Zoom 88 Large Distal Platform	TracStar Large Distal Platform ZOOM 88 Large Distal Platform ZOOM 88-T Large Distal Platform	EagleRay Long Sheath EagleRay Access Catheter
510(k) Number	K212224	K203764	K180169
Indications for Use	The TracStar LDP Large Distal Platform is indicated for the introduction of interventional devices into the peripheral, coronary, and neuro vasculature. The Zoom 88 Large Distal Platform is indicated for the introduction of interventional devices into the peripheral, coronary, and neuro vasculature.	The TracStar Large Distal Platform is indicated for the introduction of interventional devices into the peripheral, coronary, and neuro vasculature. The ZOOM 88 and ZOOM 88-T Large Distal Platform are indicated for the introduction of interventional devices into the peripheral, coronary, and neuro vasculature.	The EagleRay Long Sheath and EagleRay Access Catheter are indicated for the introduction of interventional devices into the peripheral, coronary, and neuro vasculature.
Condition Supplied	Sterile and Single Use	Same	Same
Sterilization Method	Ethylene Oxide (EtO), SAL 10 ⁻⁶	Same	Same
Inner Diameter (Distal)	0.088"	Same	Same
Outer Diameter (Distal)	0.106"	Same	Same
Inner Diameter (Proximal)	0.088"	Same	Same
Outer Diameter (Proximal)	0.110"	Same	Same

Device Attribute	Subject device	Predicate device(s)	
Effective Length	80 - 110cm	Same	Same
Tip Design	Beveled distal edge, soft, flexible, atraumatic tip	Same	Same
Distal Catheter Shaft	Additional polymer reinforcement	Reinforced with metals and polymers	Reinforced with metals and polymers
Proximal Catheter Shaft	Additional radial reinforcement	Reinforced with metals and polymers	Reinforced with metals and polymers
Coating	Hydrophilic coating	Same	Same
Materials	Commonly used medical grade plastics & metals with hydrophilic coating	Same	Same
Packaged Accessories	Rotating Hemostasis Valve (RHV)	Same	Same
Packaging Configuration	The catheters are placed in a protective polyethylene tube, mounted with accessory RHV onto a polyethylene packaging card, placed into a pouch, sealed and labeled. The sealed pouch and IFU are placed in a labeled shelf carton box.	Same	Same

H. Performance Data Supporting Substantial Equivalence:

Bench and Laboratory (in-vitro) testing was completed to evaluate the differences between the subject LDP Catheters and predicate LDP Catheters. Performance specifications and test methods were based primarily on catheter performance standard ISO 10555-1 and a summary of the evaluated performance tests and specifications is presented in **Table 2**.

The test results were reviewed and found to demonstrate that the differences between the subject LDP Catheters and predicate LDP Catheters do not significantly impact any performance parameters that would negatively affect the safety or effectiveness of the subject LDP Catheters.

Table 2: Tests and Performance Specifications

Test Attribute	Specification	Results
Delivery, Compatibility, and Retraction (Trackability)	The catheter shall be able to be delivered, deployed, and retracted per the IFU within a simulated neurological model without incurring any damage to the catheter.	Pass
Flexibility and Kink Resistance	There shall be no kinking of shaft (permanent deformation) after simulated use.	Pass
Compatibility with other Devices (external)	The catheters shall be able to be delivered through the minimum introducer sheath or guide catheter size indicated in the product labeling.	Pass
Guidewire Compatibility	The catheters shall be able to be delivered over the maximum size guidewire indicated in the product labeling.	Pass
Interventional Device Compatibility (internal)	The catheters shall be able to accommodate other interventional devices (e.g., support catheter, diagnostic catheter) up to the maximum size indicated in the product labeling.	Pass
Luer Compatibility	Devices and accessories shall be compatible with standard syringe luer fittings per ISO 80369-7.	Pass
Accessory Compatibility	Devices shall be compatible with an RHV.	Pass
Catheter Bond Strength	The catheter shall have sufficient bond strengths to remain intact throughout a procedure.	Pass
Freedom from Leakage – positive pressure	No liquid leakage from the hub or catheter shaft at 46psi for 30 seconds	Pass
Freedom from Leakage – negative pressure	No air leakage into a 20cc syringe when vacuum pulled for 15 seconds.	Pass
Dynamic Burst Pressure	Catheter does not burst under pressures that could be seen when performing contrast injections with a standard 10cc syringe.	Pass
Static Burst Pressure	Catheter does not burst under pressures that could be seen when performing contrast injections with a standard 10cc syringe.	Pass

Test Attribute	Specification	Results
Catheter Torque Strength	With the catheter tip held in a static position, there shall be no separation of any portion of the catheter when rotated at the hub at least two (2) full rotations (720 degrees).	Pass
Kink Resistance	There shall be no kinking of the catheter shaft (permanent deformation) after wrapping around anatomically relevant bend radii.	Pass
Pushability	The proximal shaft of the catheters shall have sufficient stiffness that the user can easily push the catheter to the target anatomy without buckling.	Pass
Access Force	Catheters shall not require excessive force to safely navigate and track to the target anatomy.	Pass

I. Biocompatibility Testing:

There are no changes to patient contacting materials compared to the predicate device. Therefore, the original testing on the predicate devices applies to the subject devices and additional biocompatibility testing was not required.

J. Sterilization:

The LDP Catheters are sterilized using a validated EtO process with a sterility assurance level of 1×10^{-6} validated per the overkill method in accordance with ISO 11135, "Sterilization Of Health-Care Products - Ethylene Oxide - Requirements For The Development, Validation And Routine Control Of A Sterilization Process For Medical Devices".

K. Shelf Life and Packaging:

Accelerated aging testing based on ASTM F1980 was conducted to verify packaged device performance. A real time aging equivalent of 13 months was used to support a 1-year shelf life claim. Device performance was verified by functional and performance testing.

There are no changes to packaging compared to the predicate device. Therefore, the original testing on the predicate devices applies to the subject devices and additional packaging validation testing was not required.

L. Conclusions:

Where differences were identified between the subject and predicate devices, a risk assessment was completed to determine if the difference would result in new safety or effectiveness concerns. As appropriate, previous bench and laboratory testing was evaluated for applicability and either the rationale for no impact was documented or verification and validation was repeated as required.

Based on the results of the risk assessments and associated bench and laboratory testing, the subject and predicate devices are substantially equivalent and there are no new safety or effectiveness concerns. The subject device and predicate devices share the same intended use, basic technological characteristics, and performance characteristics.

Good morning Ms. Anderson,

I know you must be very busy but I'm hoping that you can help me to better understand the review process for Special 510(k)s and the impact to the review time with issuance of an Additional Information letter. I reviewed the FDA Guidance Document "FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Goals, Guidance for Industry and Food and Drug Administration Staff" issued on October 2, 2017 and was not able to locate any language which indicates a reset of the review clock to 30 days for Special 510(k)s. The guidance document indicates that the clock stops upon issuance of a request for additional information and starts again upon receipt of the information. Following this guidance, I was under the impression that the review clock would have started back up at day 20 when Document Control received the requested additional information. Any help you can provide in indicating where I missed this information is appreciated for future submissions so that I can correctly advise project teams.

In addition, is it possible that we will be receiving a response sooner than Oct.2? As always, please let me know if there is any additional information we can provide for the review.

I appreciate the time you have already spent reviewing K212224 and answering my earlier questions. Thank you in advance for taking the time to address these additional questions for my understanding.

Kind regards,

Kristin Ellis

Kristin Ellis

Regulatory Affairs Manager

[cid:image001.png@01D7AB98.B375CEE0]

M: +1.408.857.0934

E: kellis@imperativecare.com<<mailto:kellis@imperativecare.com>>

[imperativecare.com](http://www.imperativecare.com/)<<http://www.imperativecare.com/>> |
[LinkedIn](https://www.linkedin.com/company/imperativecare/)<<https://www.linkedin.com/company/imperativecare/>> |
[Twitter](https://twitter.com/imperative_care)<https://twitter.com/imperative_care> |
[YouTube](https://www.youtube.com/channel/UCOXtDHTSq28ZgSHkgtwPhyA)<<https://www.youtube.com/channel/UCOXtDHTSq28ZgSHkgtwPhyA>>

1359 Dell Avenue, Campbell, CA 95008

www.imperativecare.com<<http://www.imperativecare.com/>>

From: Anderson, Leigh <Leigh.Anderson@fda.hhs.gov>

Sent: Tuesday, September 14, 2021 1:49 PM

To: Kristin Ellis <kellis@imperativecare.com>

Cc: Nora Hadding <nhadding@imperativecare.com>; K212224@docs.fda.gov

Subject: RE: [EXTERNAL] K212224 Review Status

Dear Ms. Ellis,

Our goal is to complete review of the response within 30 days of receipt, which shows to be October 2, 2021, in our document tracking system.

Regards,

Leigh Anderson

Biomedical Engineer

Neurointerventional Devices Team

DHT5A: Division of Neurosurgical, Neurointerventional and Neurodiagnostic Devices

OHT5: Office of Neurological and Physical Medicine Devices

Office of Product Evaluation and Quality

CDRH | Food and Drug Administration

White Oak, Bldg. 66, Rm. 4276 | 10903 New Hampshire Avenue | Silver Spring, MD 20993

Ph: 301-796-5613

leigh.anderson@fda.hhs.gov<mailto:leigh.anderson@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?ID=1712&S=E<https://nam12.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.research.net%2Fs%2Fcdrhcustomerservice%3FID%3D1712%26S%3DE&data=04%7C01%7Ckellis%40imperativecare.com%7C2712fec119b64769135408d977c116f9%7Cf9bc67a2b9bd4bcc974aec60ef533fdc%7C0%7C0%7C637672493466795309%7CUnknown%7CTWFpbGZsb3d8eyJWlIjoIJC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6IklhaWwiLCJXVCi6Mn0%3D%7C1000&sdata=033TWBtI7thuFv2GZKE5ZSh4WFzZVx%2BIvxcTvAn3QIc%3D&reserved=0>>

THIS MESSAGE IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review, disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify the sender by e-mail or phone.

From: Kristin Ellis <kellis@imperativecare.com<mailto:kellis@imperativecare.com>>

Sent: Tuesday, September 14, 2021 12:45 PM

To: Anderson, Leigh <Leigh.Anderson@fda.hhs.gov<mailto:Leigh.Anderson@fda.hhs.gov>>

Cc: Nora Hadding <nhadding@imperativecare.com<mailto:nhadding@imperativecare.com>>; K212224@docs.fda.gov<mailto:K212224@docs.fda.gov>

Subject: RE: [EXTERNAL] K212224 Review Status

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Dear Ms. Anderson,

Thank you for the correction of the review clock day. Can you please provide me with the submission timing review goal for this Special 510(k)? This would be helpful for our planning purposes.

Kind regards,

Kristin Ellis

Regulatory Affairs Manager

[cid:image001.png@01D7AB98.B375CEE0]

M: +1.408.857.0934

E: kellis@imperativecare.com<<mailto:kellis@imperativecare.com>>

[imperativecare.com](http://www.imperativecare.com/)<<http://www.imperativecare.com/>> |
LinkedIn<<https://nam12.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.linkedin.com%2Fcompany%2Fimperativecare%2F&data=04%7C01%7Ckellis%40imperativecare.com%7C2712fec119b64769135408d977c116f9%7Cf9bc67a2b9bd4bcc974aec60ef533fdc%7C0%7C0%7C637672493466805262%7CUnknown%7CTWFpbGZsb3d8eyJWJoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6IklhaWwiLCJXVCi6Mn0%3D%7C1000&sdata=uY%2BhW5R2%2BLtQhSZS3ItjT5i5v%2FC2tOCXPQX6E6XguVQ%3D&reserved=0>> |
Twitter<https://nam12.safelinks.protection.outlook.com/?url=https%3A%2F%2Ftwitter.com%2Fimperative_care&data=04%7C01%7Ckellis%40imperativecare.com%7C2712fec119b64769135408d977c116f9%7Cf9bc67a2b9bd4bcc974aec60ef533fdc%7C0%7C0%7C637672493466805262%7CUnknown%7CTWFpbGZsb3d8eyJWJoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6IklhaWwiLCJXVCi6Mn0%3D%7C1000&sdata=%2F1XM%2BdUKuH2nHBxQd0u7sh4HzRJzkdMTxIH7gvq6ZJo%3D&reserved=0> |
YouTube<<https://www.youtube.com/channel/UCOXtDHTSq28ZgSHkgtwPhyA>>

1359 Dell Avenue, Campbell, CA 95008

www.imperativecare.com<<http://www.imperativecare.com/>>

From: Anderson, Leigh <Leigh.Anderson@fda.hhs.gov<<mailto:Leigh.Anderson@fda.hhs.gov>>>

Sent: Tuesday, September 14, 2021 9:22 AM

To: Kristin Ellis <kellis@imperativecare.com<<mailto:kellis@imperativecare.com>>>

Cc: Nora Hadding <nhadding@imperativecare.com<<mailto:nhadding@imperativecare.com>>>;
K212224@docs.fda.gov<<mailto:K212224@docs.fda.gov>>

Subject: RE: [EXTERNAL] K212224 Review Status

Dear Ms. Ellis,

Thank you for your email.

Our review tracking system indicates that today is day 31 of FDA's review clock for K212224. The submission is still under review at this time. If we have additional questions, we will reach out as soon as possible.

Regards,

Leigh Anderson

Biomedical Engineer

Neurointerventional Devices Team

DHT5A: Division of Neurosurgical, Neurointerventional and Neurodiagnostic Devices

OHT5: Office of Neurological and Physical Medicine Devices

Office of Product Evaluation and Quality

CDRH | Food and Drug Administration

White Oak, Bldg. 66, Rm. 4276 | 10903 New Hampshire Avenue | Silver Spring, MD 20993

Ph: 301-796-5613

leigh.anderson@fda.hhs.gov<<mailto:leigh.anderson@fda.hhs.gov>>

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received:

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

<https://www.research.net/s/cdrhcustomerservice?ID=1712&S=E<https://nam12.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.research.net%2Fs%2Fcdrhcustomerservice%3FID%3D1712%26S%3DE&data=04%7C01%7Ckellis%40imperativecare.com%7C2712fec119b64769135408d977c116f9%7Cf9bc67a2b9bd4bcc974aec60ef533fdc%7C0%7C0%7C637672493466805262%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6IklhaWwiLCJXVCi6Mn0%3D%7C1000&sdata=KvZ9CePqzgfpo52cRkT%2BYOlUfugdGExl4A3s0La0J9w%3D&reserved=0>>

THIS MESSAGE IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review, disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify the sender by e-mail or phone.

From: Kristin Ellis <kellis@imperativecare.com<mailto:kellis@imperativecare.com>>
Sent: Tuesday, September 14, 2021 11:48 AM
To: Anderson, Leigh <Leigh.Anderson@fda.hhs.gov<mailto:Leigh.Anderson@fda.hhs.gov>>
Cc: Nora Hadding <nadding@imperativecare.com<mailto:nadding@imperativecare.com>>
Subject: [EXTERNAL] K212224 Review Status

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Good morning Ms. Anderson,

I hope this email finds you well. I am contacting you with regards to the review status of K212224. With the request for additional information hold and the Labor Day holiday, I am unsure of the review clock day count. I believe the clock is currently at Day 32. Can you please confirm if this is correct or if not, what date is the end of the review cycle?

Additionally, please let me know if there is any further information you require to complete the review.

Kind regards,

Kristin Ellis

Regulatory Affairs Manager

[cid:image001.png@01D7AB98.B375CEE0]

M: +1.408.857.0934

E: kellis@imperativecare.com<mailto:kellis@imperativecare.com>

imperativecare.com<<http://www.imperativecare.com/>> |
LinkedIn<<https://nam12.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.linkedin.com%2Fcompany%2Fimperativecare%2F&data=04%7C01%7Ckellis%40imperativecare.com%7C2712fec119b64769135408d977c116f9%7Cf9bc67a2b9bd4bcc974aec60ef533fdc%7C0%7C0%7C637672493466815218%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6IklhaWwiLCJXVCi6Mn0%3D%7C1000&sdata=JlUtdFk6whPDRrbyHxBL3fq1TDY10ez3C5FfnNN6sZk%3D&reserved=0>>> |
Twitter<https://nam12.safelinks.protection.outlook.com/?url=https%3A%2F%2Ftwitter.com%2Fimperative_care&data=04%7C01%7Ckellis%40imperativecare.com%7C2712fec119b64769135408d977c116f9%7Cf9bc67a2b9bd4bcc974aec60ef533fdc%7C0%7C0%7C637672493466815218%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6IklhaWwiLCJXVCi6Mn0%3D%7C1000&sdata=wlg82Kfnbyr5IdsBC5ZOX0pULjWUUIPX%2BvUnGBgK%2B2w%3D&reserved=0>> |

YouTube<<https://www.youtube.com/channel/UCOXtDHTSq28ZgSHkgtwPhyA>>

1359 Dell Avenue, Campbell, CA 95008

www.imperativecare.com<<http://www.imperativecare.com/>>

Dear Ms. Ellis,

I am lead reviewer for K212224 for the TracStar and Zoom 88 Large Distal Platform Catheters. We are still early in our review and primarily in the administrative RTA review phase. We have noticed that the following (b)(4)

We request that you provide a response to the following items via email by Monday, July 26 to facilitate our review. If you have concerns with the proposed timeline, please let me know.

FDA Request:

(b)(4)

Regards,

Leigh Anderson
Biomedical Engineer
Neurointerventional Devices Team
DHTSA: Division of Neurosurgical, Neurointerventional and Neurodiagnostic Devices
OHTS: Office of Neurological and Physical Medicine Devices
Office of Product Evaluation and Quality
CDRH | Food and Drug Administration
White Oak, Bldg. 66, Rm. 4276 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-5613
leigh.anderson@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?ID=1712&S=E>

THIS MESSAGE IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review, disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify the sender by e-mail or phone.

Records processed under FOIA Request 2023-10349; Released by CDRH on 09-19-2024

Imperative
CARE

TracStar LDP™
LARGE DISTAL PLATFORM

1 TRX™ Tip

14cm Hydrophilic Coating Length

Ø 8F (.110 in/2.79 mm)

105 cm

Ø 6F (.088 in/2.24mm)

1 REF

REF ICAC068105

LOT 000000

2018-08-15

01: 0 0512212 03034 4 (17) 180815 (15) 000000

STERILE

Attention - See instructions for use for safety information and symbols glossary

Rx Only Prescription only - U.S. Federal law restricts this device to use by or on the order of a physician

REF ICAC068105 **LOT** 000000

01: 0 0512212 03034 4 (17) 180815 (15) 000000

Imperative Care, Inc. TracStar™ 8F 105 LDP, 105 cm

REF ICAC068105 **LOT** 000000

01: 0 0512212 03034 4 (17) 180815 (15) 000000

Imperative Care, Inc. TracStar™ 8F 105 LDP, 105 cm

REF ICAC068105 **LOT** 000000

01: 0 0512212 03034 4 (17) 180815 (15) 000000

Imperative Care, Inc. TracStar™ 8F 105 LDP, 105 cm

IMPERATIVE CARE, INC.
1399 Dell Avenue
Campbell CA 95008 U.S.A.
+1 408 502 7348
© 2018 Imperative Care, Inc. All Rights Reserved

FG00541-04
(b)(4)

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

Dear Ms. Ellis,

Thank you for providing an interactive response with more (b)(4)
(b)(4) I confirm receipt.

Regards,

Leigh Anderson

Biomedical Engineer

Neurointerventional Devices Team

DHT5A: Division of Neurosurgical, Neurointerventional and Neurodiagnostic Devices

OHT5: Office of Neurological and Physical Medicine Devices

Office of Product Evaluation and Quality

CDRH | Food and Drug Administration

White Oak, Bldg. 66, Rm. 4276 | 10903 New Hampshire Avenue | Silver Spring, MD 20993

Ph: 301-796-5613

leigh.anderson@fda.hhs.gov<mailto:leigh.anderson@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?ID=1712&S=E>

THIS MESSAGE IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review, disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify the sender by e-mail or phone.

From: Kristin Ellis <kellis@imperativecare.com>

Sent: Saturday, July 24, 2021 9:37 PM

To: Anderson, Leigh <Leigh.Anderson@fda.hhs.gov>

Cc: K212224@docs.fda.gov; Nora Hadding <nadding@imperativecare.com>

Subject: [EXTERNAL] RE: K212224 - Interactive Request
(Please Reply by Mon Jul 26)

(b)(4)

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Dear Ms. Anderson,

Attached please find the response to FDA's Interactive Request for the (b)(4)
(b)(4) Please let me know if you have further questions or need any further clarification.

Kind regards,

Kristin Ellis

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

Regulatory Affairs Manager

[cid:image001.png@01D781EF.D9C45AD0]

M: +1.408.857.0934

E: kellis@imperativecare.com<<mailto:kellis@imperativecare.com>>

[imperativecare.com](http://www.imperativecare.com/)<<http://www.imperativecare.com/>> |

LinkedIn<<https://www.linkedin.com/company/imperativecare/>> |

Twitter<https://twitter.com/imperative_care> |

YouTube<<https://www.youtube.com/channel/UCOXtDHTSq28ZgSHkgtwPhyA>>

1359 Dell Avenue, Campbell, CA 95008

www.imperativecare.com<<http://www.imperativecare.com/>>

From: Anderson, Leigh <Leigh.Anderson@fda.hhs.gov<<mailto:Leigh.Anderson@fda.hhs.gov>>>

Sent: Friday, July 23, 2021 7:38 AM

To: Kristin Ellis <kellis@imperativecare.com<<mailto:kellis@imperativecare.com>>>

Cc: K212224@docs.fda.gov<<mailto:K212224@docs.fda.gov>>

Subject: K212224 - Interactive Request - (b)(4) (Please Reply by Mon Jul 26)

Dear Ms. Ellis,

I am lead reviewer for K212224 for the TracStar and Zoom 88 Large Distal Platform Catheters. We are still early in our review and primarily in the administrative RTA review phase. We have noticed that the following (b)(4)

(b)(4)

We request that you provide a response to the following items via email by Monday, July 26 to facilitate our review. If you have concerns with the proposed timeline, please let me know.

FDA Request:

(b)(4)

(b)(4)

Regards,

Leigh Anderson

Biomedical Engineer

Neurointerventional Devices Team

DHT5A: Division of Neurosurgical, Neurointerventional and Neurodiagnostic Devices

OHT5: Office of Neurological and Physical Medicine Devices

Office of Product Evaluation and Quality

CDRH | Food and Drug Administration

White Oak, Bldg. 66, Rm. 4276 | 10903 New Hampshire Avenue | Silver Spring, MD 20993

Ph: 301-796-5613

leigh.anderson@fda.hhs.gov<<mailto:leigh.anderson@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?ID=1712&S=E<https://nam12.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.research.net%2Fs%2Fcdrhcustomerservice%3FID%3D1712%26S%3DE&data=04%7C01%7Ckellis%40imperativecare.com%7C1f3fe5b3742d4fa4a2ae08d94de77197%7Cf9bc67a2b9bd4bcc974aec60ef533fdc%7C0%7C0%7C637626478724862288%7CUnknown%7CTWFpbGZsb3d8eyJWlIjoIJC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6IklhaWwiLCJXVCI6Mn0%3D%7C1000&sdata=C PbWH3eMkVejSbGvr2%2BxV13E5WtYb70Pky%2BAKrBkjqc%3D&reserved=0>

THIS MESSAGE IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review, disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify the sender by e-mail or phone.



U.S. FOOD & DRUG
ADMINISTRATION

September 20, 2021

Imperative Care, Inc.
Kristin Ellis
Regulatory Affairs Manager
1359 Dell Avenue
Campbell, California 95008

Re: K212224

Trade/Device Name: TracStar LDP Large Distal Platform; Zoom 88 Large Distal Platform
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: QJP, DQY
Dated: September 1, 2021
Received: September 2, 2021

Dear Kristin Ellis:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm> identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part

801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see <https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products>); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance>) and CDRH Learn (<https://www.fda.gov/training-and-continuing-education/cdrh-learn>). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice>) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,


Naira Muradyan -S

Naira Muradyan, Ph.D.
Assistant Director
DHT5A: Division of Neurosurgical,
Neurointerventional
and Neurodiagnostic Devices
OHT5: Office of Neurological
and Physical Medicine Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Records processed under FOIA Request 2023-10349; Released by CDRH on 09-19-2024



Dear Ms. Ellis,

Thanks for your email.

You are correct that the Special 510(k) guidance document notes that FDA generally intends to review Special 510(k) submissions within 30 days of receipt. However, we have not been able to complete our review by FDA day 30 for K212224, as the submission is on day 34 of FDA review today.

Just to clarify, the FDA review clock did not reset to 0 after the Additional Information (AINN) response was received, but continued counting from the day of the AINN request (day 19) for K212224. We intend to complete our review within 30 days of receipt of the response, or by October 2, 2021, for K212224 (which would be day 49). It is certainly possible we complete our review sooner than that date, but I cannot confirm a specific date for our review decision. I don't think the potential for the review to take up to an additional 30 days upon receipt of the AINN response is described in any specific document or webpage.

Regards,

Leigh Anderson

Biomedical Engineer

Neurointerventional Devices Team

DHT5A: Division of Neurosurgical, Neurointerventional and Neurodiagnostic Devices

OHT5: Office of Neurological and Physical Medicine Devices

Office of Product Evaluation and Quality

CDRH | Food and Drug Administration

White Oak, Bldg. 66, Rm. 4276 | 10903 New Hampshire Avenue | Silver Spring, MD 20993

Ph: 301-796-5613

leigh.anderson@fda.hhs.gov<mailto:leigh.anderson@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?ID=1712&S=E>

THIS MESSAGE IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review, disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify the sender by e-mail or phone.

From: Kristin Ellis <kellis@imperativecare.com>

Sent: Friday, September 17, 2021 10:51 AM

To: Anderson, Leigh <Leigh.Anderson@fda.hhs.gov>

Cc: Nora Hadding <nhadding@imperativecare.com>; K212224@docs.fda.gov

Subject: RE: [EXTERNAL] K212224 Review Status

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Good morning Ms. Anderson,

I know you must be very busy but I'm hoping that you can help me to better understand the review process for Special 510(k)s and the impact to the review time with issuance of an Additional Information letter. I reviewed the FDA Guidance Document "FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Goals, Guidance for Industry and Food and Drug Administration Staff" issued on October 2, 2017 and was not able to locate any language which indicates a reset of the review clock to 30 days for Special 510(k)s. The guidance document indicates that the clock stops upon issuance of a request for additional information and starts again upon receipt of the information. Following this guidance, I was under the impression that the review clock would have started back up at day 20 when Document Control received the requested additional information. Any help you can provide in indicating where I missed this information is appreciated for future submissions so that I can correctly advise project teams.

In addition, is it possible that we will be receiving a response sooner than Oct.2? As always, please let me know if there is any additional information we can provide for the review.

I appreciate the time you have already spent reviewing K212224 and answering my earlier questions. Thank you in advance for taking the time to address these additional questions for my understanding.

Kind regards,

Kristin Ellis

Kristin Ellis

Regulatory Affairs Manager

[cid:image001.png@01D7ABCC.BD4D0B20]

M: +1.408.857.0934

E: kellis@imperativecare.com<<mailto:kellis@imperativecare.com>>

<http://www.imperativecare.com/> |

LinkedIn<<https://www.linkedin.com/company/imperativecare/>> |

Twitter<https://twitter.com/imperative_care> |

YouTube<<https://www.youtube.com/channel/UCOXtDHTSq28ZgSHkgtwPhyA>>

1359 Dell Avenue, Campbell, CA 95008

www.imperativecare.com<<http://www.imperativecare.com/>>

From: Anderson, Leigh <Leigh.Anderson@fda.hhs.gov<<mailto:Leigh.Anderson@fda.hhs.gov>>>

Sent: Tuesday, September 14, 2021 1:49 PM

To: Kristin Ellis <kellis@imperativecare.com<<mailto:kellis@imperativecare.com>>>

Cc: Nora Hadding <nhadding@imperativecare.com<<mailto:nhadding@imperativecare.com>>>;
K212224@docs.fda.gov<<mailto:K212224@docs.fda.gov>>

Subject: RE: [EXTERNAL] K212224 Review Status

Dear Ms. Ellis,

Our goal is to complete review of the response within 30 days of receipt, which shows to be October 2, 2021, in our document tracking system.

Regards,

Leigh Anderson

Biomedical Engineer

Neurointerventional Devices Team

DHT5A: Division of Neurosurgical, Neurointerventional and Neurodiagnostic Devices

OHT5: Office of Neurological and Physical Medicine Devices

Office of Product Evaluation and Quality

CDRH | Food and Drug Administration

White Oak, Bldg. 66, Rm. 4276 | 10903 New Hampshire Avenue | Silver Spring, MD 20993

Ph: 301-796-5613

leigh.anderson@fda.hhs.gov<mailto:leigh.anderson@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?ID=1712&S=E<https://nam12.safelinks.protocol.outlook.com/?url=https%3A%2F%2Fwww.research.net%2Fs%2Fcdrhcustomerservice%3FID%3D1712%26S%3DE&data=04%7C01%7Ckellis%40imperativecare.com%7C2712fec119b64769135408d977c116f9%7Cf9bc67a2b9bd4bcc974aec60ef533fdc%7C0%7C0%7C637672493466795309%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6IklhaWwiLCJXVCi6Mn0%3D%7C1000&sdata=033TWBtI7thuFv2GZKE5ZSh4WFzZVx%2BIvxcTvAn3QIc%3D&reserved=0>>

THIS MESSAGE IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review, disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify the sender by e-mail or phone.

From: Kristin Ellis <kellis@imperativecare.com<mailto:kellis@imperativecare.com>>

Sent: Tuesday, September 14, 2021 12:45 PM

To: Anderson, Leigh <Leigh.Anderson@fda.hhs.gov<mailto:Leigh.Anderson@fda.hhs.gov>>

Cc: Nora Hadding <nhadding@imperativecare.com<mailto:nhadding@imperativecare.com>>; K212224@docs.fda.gov<mailto:K212224@docs.fda.gov>

Subject: RE: [EXTERNAL] K212224 Review Status

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Dear Ms. Anderson,

Thank you for the correction of the review clock day. Can you please provide me with the submission timing review goal for this Special 510(k)? This would be helpful for our planning purposes.

Kind regards,

Kristin Ellis

Regulatory Affairs Manager

[cid:image001.png@01D7ABCC.BD4D0B20]

M: +1.408.857.0934

E: kellis@imperativecare.com<mailto:kellis@imperativecare.com>

imperativecare.com<http://www.imperativecare.com/> |
LinkedIn<https://nam12.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.linkedin.com%2Fcompany%2Fimperativecare%2F&data=04%7C01%7Ckellis%40imperativecare.com%7C2712fec119b64769135408d977c116f9%7Cf9bc67a2b9bd4bcc974aec60ef533fdc%7C0%7C0%7C637672493466805262%7CUnknown%7CTWFpbGZsb3d8eyJWIjoIMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6IklhaWwiLCJXVCi6Mn0%3D%7C1000&sdata=uY%2BhW5R2%2BLtQhSZS3ItjT5i5v%2FC2tOCXPQX6E6XguVQ%3D&reserved=0> |
Twitter<https://nam12.safelinks.protection.outlook.com/?url=https%3A%2F%2Ftwitter.com%2Fimperative_care&data=04%7C01%7Ckellis%40imperativecare.com%7C2712fec119b64769135408d977c116f9%7Cf9bc67a2b9bd4bcc974aec60ef533fdc%7C0%7C0%7C637672493466805262%7CUnknown%7CTWFpbGZsb3d8eyJWIjoIMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6IklhaWwiLCJXVCi6Mn0%3D%7C1000&sdata=%2F1XM%2BdUKuH2nHBxQd0u7sh4HzRJzkdMTxIH7gvq6ZJo%3D&reserved=0> |
YouTube<https://www.youtube.com/channel/UCOXtDHTSq28ZgSHkgtwPhyA>

1359 Dell Avenue, Campbell, CA 95008

www.imperativecare.com<http://www.imperativecare.com/>

From: Anderson, Leigh <Leigh.Anderson@fda.hhs.gov<mailto:Leigh.Anderson@fda.hhs.gov>>

Sent: Tuesday, September 14, 2021 9:22 AM

To: Kristin Ellis <kellis@imperativecare.com<mailto:kellis@imperativecare.com>>

Cc: Nora Hadding <nhadding@imperativecare.com<mailto:nhadding@imperativecare.com>>; K212224@docs.fda.gov<mailto:K212224@docs.fda.gov>

Subject: RE: [EXTERNAL] K212224 Review Status

Dear Ms. Ellis,

Thank you for your email.

Our review tracking system indicates that today is day 31 of FDA's review clock for K212224. The submission is still under review at this time. If we have additional questions, we will reach out as soon as possible.

Regards,

Leigh Anderson

Biomedical Engineer

Neurointerventional Devices Team

DHT5A: Division of Neurosurgical, Neurointerventional and Neurodiagnostic Devices

OHT5: Office of Neurological and Physical Medicine Devices

Office of Product Evaluation and Quality

CDRH | Food and Drug Administration

White Oak, Bldg. 66, Rm. 4276 | 10903 New Hampshire Avenue | Silver Spring, MD 20993

Ph: 301-796-5613

leigh.anderson@fda.hhs.gov<mailto:leigh.anderson@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?ID=1712&S=E<https://nam12.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.research.net%2Fs%2Fcdrhcustomerservice%3FID%3D1712%26S%3DE&data=04%7C01%7Ckellis%40imperativecare.com%7C2712fec119b64769135408d977c116f9%7Cf9bc67a2b9bd4bcc974aec60ef533fdc%7C0%7C0%7C637672493466805262%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6IklhaWwiLCJXVCi6Mn0%3D%7C1000&sdata=KvZ9CePqzgfpo52cRkT%2BYOlUfugdGExl4A3s0La0J9w%3D&reserved=0>>

THIS MESSAGE IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review, disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify the sender by e-mail or phone.

From: Kristin Ellis <kellis@imperativecare.com<mailto:kellis@imperativecare.com>>

Sent: Tuesday, September 14, 2021 11:48 AM

To: Anderson, Leigh <Leigh.Anderson@fda.hhs.gov<mailto:Leigh.Anderson@fda.hhs.gov>>

Cc: Nora Hadding <nhadding@imperativecare.com<mailto:nhadding@imperativecare.com>>

Subject: [EXTERNAL] K212224 Review Status

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Good morning Ms. Anderson,

I hope this email finds you well. I am contacting you with regards to the review status of K212224. With the request for additional information hold and the Labor Day holiday, I am unsure of the review clock day count. I believe the clock is currently at Day 32. Can you please confirm if this is correct or if not, what date is the end of the review cycle?

Additionally, please let me know if there is any further information you require to complete the review.

Kind regards,

Kristin Ellis

Regulatory Affairs Manager

[cid:image001.png@01D7ABCC.BD4D0B20]

M: +1.408.857.0934

E: kellis@imperativecare.com<mailto:kellis@imperativecare.com>

imperativecare.com<http://www.imperativecare.com/> |
LinkedIn<https://nam12.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.linkedin.com%2Fcompany%2Fimperativecare%2F&data=04%7C01%7Ckellis%40imperativecare.com%7C2712fec119b64769135408d977c116f9%7Cf9bc67a2b9bd4bcc974aec60ef533fdc%7C0%7C0%7C637672493466815218%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6IklhaWwiLCJXVCi6Mn0%3D%7C1000&sdata=JlUtdFk6whPDRrbyHxBL3fq1TDY10ez3C5FfnNN6sZk%3D&reserved=0> |
Twitter<https://nam12.safelinks.protection.outlook.com/?url=https%3A%2F%2Ftwitter.com%2Fimperative_care&data=04%7C01%7Ckellis%40imperativecare.com%7C2712fec119b64769135408d977c116f9%7Cf9bc67a2b9bd4bcc974aec60ef533fdc%7C0%7C0%7C637672493466815218%7CUnknown%7CTWF

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

pbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C1000&sdat
a=wlG82Kfnbyr5IdsBC5ZOX0pULjWUUIPX%2BvUnGBgK%2B2w%3D&reserved=0> |
YouTube<<https://www.youtube.com/channel/UCOXtDHTSq28ZgSHkgtwPhyA>>

1359 Dell Avenue, Campbell, CA 95008

www.imperativecare.com<<http://www.imperativecare.com/>>

Dear Ms. Anderson,

Attached please find the response to FDA's Interactive Request for the (b)(4) (b)(4). Please let me know if you have further questions or need any further clarification.

Kind regards,

Kristin Ellis

Regulatory Affairs Manager

[cid:image001.png@01D780BA.BE3892D0]

M: +1.408.857.0934

E: kellis@imperativecare.com<<mailto:kellis@imperativecare.com>>

[imperativecare.com](http://www.imperativecare.com/)<<http://www.imperativecare.com/>> |

LinkedIn<<https://www.linkedin.com/company/imperativecare/>> |

Twitter<https://twitter.com/imperative_care> |

YouTube<<https://www.youtube.com/channel/UCOXtDHTSq28ZgSHkgtwPhyA>>

1359 Dell Avenue, Campbell, CA 95008

www.imperativecare.com<<http://www.imperativecare.com/>>

From: Anderson, Leigh <Leigh.Anderson@fda.hhs.gov>

Sent: Friday, July 23, 2021 7:38 AM

To: Kristin Ellis <kellis@imperativecare.com>

Cc: K212224@docs.fda.gov

Subject: K212224 - Interactive Request - (b)(4) (Please Reply by Mon Jul 26)

Dear Ms. Ellis,

I am lead reviewer for K212224 for the TracStar and Zoom 88 Large Distal Platform Catheters. We are still early in our review and primarily in the administrative RTA review phase. We have noticed that the following (b)(4)

(b)(4)

We request that you provide a response to the following items via email by Monday, July 26 to facilitate our review. If you have concerns with the proposed timeline, please let me know.

FDA Request:

(b)(4)

(b)(4)

Regards,

Leigh Anderson

Biomedical Engineer

Neurointerventional Devices Team

DHT5A: Division of Neurosurgical, Neurointerventional and Neurodiagnostic Devices

OHT5: Office of Neurological and Physical Medicine Devices

Office of Product Evaluation and Quality

CDRH | Food and Drug Administration

White Oak, Bldg. 66, Rm. 4276 | 10903 New Hampshire Avenue | Silver Spring, MD 20993

Ph: 301-796-5613

leigh.anderson@fda.hhs.gov<<mailto:leigh.anderson@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?ID=1712&S=E<https://nam12.safelinks.protocol.outlook.com/?url=https%3A%2F%2Fwww.research.net%2Fs%2Fcdrhcustomerservice%3FID%3D1712%26S%3DE&data=04%7C01%7Ckellis%40imperativecare.com%7C1f3fe5b3742d4fa4a2ae08d94de77197%7Cf9bc67a2b9bd4bcc974aec60ef533fdc%7C0%7C0%7C637626478724862288%7CUnknown%7CTWFpbGZsb3d8eyJWlIjoIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6IklhaWwiLCJXVCi6Mn0%3D%7C1000&sdata=C PbW3eMkVejSbGvr2%2BxV13E5WtYb70Pky%2BAKrBkjqc%3D&reserved=0>>

THIS MESSAGE IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review, disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify

Records processed under FOIA Request 2023-10349; Released by CDRH on 09-19-2024
the sender by e-mail or phone.



imperativecare.com
1359 Dell Avenue
Campbell, CA 95008

W: +1 669.235.8155
F: +1 669.265.0412
E: info@imperativecare.com

FDA/CDRH/DCC

JUL 16 2021

RECEIVED

July 15, 2021

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – W066-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

K212224

Attn: Neuro-interventional Devices Branch
Division of Neurological and Physical Medicine Devices
Office of Device Evaluation

**RE: Special 510(k) Notification, Imperative Care Large Distal Platform (LDP) Catheters
– Changes Made Under Design Controls**

Enclosed is a Special 510(k) for proposed design and manufacturing modifications for the Imperative Care LDP catheters cleared under 510(k) K203764. Modifications to the catheter include dimensional updates, additional axial and radial reinforcements (b)(4) and manufacturing process improvements.

The Imperative Care LDP Catheters are Class II devices per 21 CFR 870.1250, Product Code QJP and DQY. The LDP Catheters included in this premarket notification are listed in the following table:

Trade Name (Proprietary Name)	Model Number	Size (ID x Working Length)
Zoom™ 88 Large Distal Platform	ICTC088100	0.088" x100cm
	ICTC088110	0.088" x110cm
TracStar™ Large Distal Platform	ICAC088080	0.088" x80cm
	ICAC088090	0.088" x90cm
	ICAC088095	0.088" x95cm
	ICAC088105	0.088" x105cm

To facilitate the review of this Special 510(k) notification, this submission has been formatted in accordance with the guidelines presented in the FDA guidance documents titled:



- *The Special 510(k) Program: Guidance for Industry and FDA Staff* issued September 13, 2019
- *Refuse to Accept Policy for 510(k)s: Guidance for Industry and FDA Staff* issued September 13, 2019
- *Recommended Content and Format of Non-Clinical Bench Performance Testing Information in Premarket Submissions* issued December 20, 2019

As required by the Medical Device User Fee and Modernization Act (MDUFA), a Medical Device User Fee has been electronically submitted. A copy of the Medical Device User Fee Cover Sheet is included in Section 1.0 of this submission.

One electronic copy (eCopy) of this submission is provided per FDA Guidance Document *eCopy Program for Medical Device Submissions Guidance for Industry and Food and Drug Administration Staff* issued April 27, 2020. The existence of this Premarket Notification is confidential, and the protection afforded to such confidential information by 21 CFR 807.95 (b), 18 USC 1905, 21 USC 331 (I), 5 USC 552, and other applicable laws is hereby claimed.

Your consideration of this Special 510(k) notification is appreciated. Should you have any questions or require further information, please contact me at (408) 857-0934 or via email at kellis@imperativecare.com. In my absence, please contact Nora Hadding, Senior Vice President, Clinical Affairs, Regulatory Affairs, and Quality Assurance at (b)(6) or via email at nhadding@imperativecare.com.

Sincerely,

(b)(6)

Kristin Ellis

Regulatory Affairs Manager

Imperative Care Inc.

Cc: Nora Hadding, Senior Vice President, Clinical Affairs, Regulatory Affairs, and Quality Assurance

Dear Ms. Anderson,

Thank you for acknowledging the use of the corrected forms. Please let me know if you have any other questions or need further information.

Kind regards,

Kristin Ellis
Regulatory Affairs Manager



M: +1.408.857.0934
E: kellis@imperativecare.com
imperativecare.com | [LinkedIn](#) | [Twitter](#) | [YouTube](#)

1359 Dell Avenue, Campbell, CA 95008
www.imperativecare.com

From: Anderson, Leigh <Leigh.Anderson@fda.hhs.gov>

Sent: Thursday, September 9, 2021 2:21 PM

To: Kristin Ellis <kellis@imperativecare.com>

Cc: K212224@docs.fda.gov

Subject: RE: [EXTERNAL] RE: K212224 - Interactive Request (b)(4)

Dear Ms. Ellis,

Thank you for your quick review and reply. We will use the latest versions I sent by email at this point moving forward.

If we have additional questions, we will reach out to you.

Regards,

Leigh Anderson
Biomedical Engineer
Neurointerventional Devices Team
DHT5A: Division of Neurosurgical, Neurointerventional and Neurodiagnostic Devices
OHT5: Office of Neurological and Physical Medicine Devices
Office of Product Evaluation and Quality
CDRH | Food and Drug Administration
White Oak, Bldg. 66, Rm. 4276 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-5613
leigh.anderson@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?ID=1712&S=E>

THIS MESSAGE IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review, disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify the sender by e-mail or phone.

From: Kristin Ellis <kellis@imperativecare.com>

Sent: Thursday, September 9, 2021 5:19 PM

To: Anderson, Leigh <Leigh.Anderson@fda.hhs.gov>

Cc: K212224@docs.fda.gov

Subject: [EXTERNAL] RE: K212224 - Interactive Request (b)(4)

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Dear Ms. Anderson,

(b)(4)

Kind regards,

Kristin Ellis
Regulatory Affairs Manager



M: +1.408.857.0934
E: kellis@imperativecare.com
imperativecare.com | [LinkedIn](#) | [Twitter](#) | [YouTube](#)

1359 Dell Avenue, Campbell, CA 95008
www.imperativecare.com

From: Anderson, Leigh <Leigh.Anderson@fda.hhs.gov>

Sent: Thursday, September 9, 2021 2:11 PM

To: Kristin Ellis <kellis@imperativecare.com>

Cc: K212224@docs.fda.gov

Subject: K212224 - Interactive Request - (b)(4)

Dear Ms. Ellis,

(b)(4)

Regards,

Leigh Anderson
Biomedical Engineer
Neurointerventional Devices Team
DHT5A: Division of Neurosurgical, Neurointerventional and Neurodiagnostic Devices
OHT5: Office of Neurological and Physical Medicine Devices
Office of Product Evaluation and Quality
CDRH | Food and Drug Administration
White Oak, Bldg. 66, Rm. 4276 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-5613
leigh.anderson@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?ID=1712&S=E>

THIS MESSAGE IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review, disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify the sender by e-mail or phone.



Food and Drug Administration
CDRH/OPEQ/OHTV/DHTVA
WO66 RM4276
10903 New Hampshire Ave
Silver Spring, MD 20993-0002
301-796-5613

Premarket Notification 510(k) Review

Date: September 9, 2021			
Reviewer: Leigh Anderson			
Subject: Special 510(k)# K212224/S001			
Applicant: Imperative Care Inc.		Device Trade Name: TracStar LDP Large Distal Platform, Zoom 88 Large Distal Platform	
Contact Name: Kristin Ellis		Contact Title: Regulatory Affairs Manager	
Correspondent Firm: Imperative Care Inc.		Phone: (408) 857-0934 Email: kellis@imperativecare.com	
Received Date: September 2, 2021		Due Date: October 2, 2021	
Pro Code(s): QJP Class: II Reg #: 870.1250		Reg Name: Percutaneous Catheter	
Pro Code(s): DQY Class: II Reg #: 870.1250		Reg Name: Percutaneous catheter	
Predicate Devices:			
Submission #	Pro Code	Device Trade Name	Applicant
K203764	QJP,	TracStar Large Distal Platform,	Imperative Care Inc.
	DQY	ZOOM 88 Large Distal Platform,	
		ZOOM 88-T Large Distal Platform	
Recommendation			
I recommend that the TracStar LDP Large Distal Platform, Zoom 88 Large Distal Platform is/are			
Substantially Equivalent (SESE)			

(b)(5)

(b)(5)

(b)(5)

(b)(5)

(b)(5)

(b)(5)

(b)(5)

(b)(5)

(b)(5)

(b)(5)

(b)(5)

(b)(5)

(b)(5)

(b)(5)

(b)(5)

(b)(5)

(b)(5)

(b)(5)

(b)(5)

(b)(5)

(b)(5)

(b)(5)

(b)(5)

(b)(5)

(b)(5)

Digital Signature Concurrence Table (Doc ID: 04500.14.05)

This document represents a high-level summary of the Agency's determination on whether the applicant's device is substantially equivalent to a legally marketed predicate device. In determining whether the subject device is substantially equivalent to a predicate device, we carefully considered the relevant regulatory and statutory criteria for Agency decision-making under 21 CFR part 807 and section 513(i) of the Federal Food, Drug and Cosmetic Act (FD&C Act). We considered the burden that may be incurred by the applicant's attempt to follow the premarket notification process. The deficiencies provided in this review, if any, represent the required minimum information necessary to support a substantial equivalence determination. Therefore, we believe that we have considered the least burdensome requirements, under section 513(i)(1)(D) of the FD&C Act, for a 510(k) determination of substantial equivalence.

Reviewer Sign-Off

Leigh B. Anderson -S

Digitally signed by Leigh B.

Anderson -S

Date: 2021.09.09 20:05:54 -04'00'

Dear Ms. Ellis,

(b)(4)

Regards,

Leigh Anderson

Biomedical Engineer

Neurointerventional Devices Team

DHT5A: Division of Neurosurgical, Neurointerventional and Neurodiagnostic Devices

OHT5: Office of Neurological and Physical Medicine Devices

Office of Product Evaluation and Quality

CDRH | Food and Drug Administration

White Oak, Bldg. 66, Rm. 4276 | 10903 New Hampshire Avenue | Silver Spring, MD 20993

Ph: 301-796-5613

leigh.anderson@fda.hhs.gov<mailto:leigh.anderson@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?ID=1712&S=E>

THIS MESSAGE IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review, disclosure,

dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify the sender by e-mail or phone.

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)



Biocompatibility Review

Memorandum

Date:	August 4, 2021
To:	Leigh Anderson, M.S., Lead Reviewer OHT5/DHT5A
From:	Dhanya Williams, M.S. Biologist/Scientific Reviewer, OHT5/DHT5A
Reviewer Electronic Signature:	Dhanya K. Williams - S Digitally signed by Dhanya K. Williams - S Date: 2021.08.04 05:42:38 -04'00'
Subject:	K212224 (Special 510(k) for modifications to devices cleared in K203764)
Applicant:	Imperative Care 1359 Dell Avenue Campbell, CA 95008
Device (Trade name):	Zoom™ 88 Large Distal Platform (LDP) Catheters TracStar™ Large Distal Platform (LDP) Catheters
Device (Regulation name):	Percutaneous Catheter
Contact:	Kristin Ellis Regulatory Affairs Manager Imperative Care Inc. Tel: 408-857-0934 Email: kellis@imperativecare.com

(b)(5)

(b)(5)

(b)(5)

(b)(5)

(b)(5)

(b)(5)

(b)(5)

(b)(5)

(b)(5)

(b)(5)

(b)(5)

(b)(5)

(b)(5)

(b)(5)

(b)(5)

(b)(5)

Food and Drug Administration

Form Approved: OMB No. 0910-0120

Expiration Date: 06/30/2023

See *PRA Statement* below.

Indications for Use

(b)(4)

From: Sumpter, Melanie * [Melanie.Sumpter@fda.hhs.gov]
Sent: 7/16/2021 6:19:26 PM
To: kellis@imperativecare.com
Subject: K212224 Acknowledgment Notification
Attachments: K212224 Letter.pdf

Sincerely,

Melanie N. Sumpter

Technical Information Specialist - 510(k) Staff

CDRH Document Control Center

Melanie.Sumpter@fda.hhs.gov



U.S. FOOD & DRUG
ADMINISTRATION

Records processed under FOIA Request 2023-10349; Released by CDRH on 09-19-2024

Acknowledgment Letter

7/16/2021

Kristin Ellis, Regulatory Affairs Manager
Imperative Care Inc.
1359 Dell Avenue
Campbell, CA 95008
UNITED STATES

Dear Kristin Ellis:

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 address listed below. Failure to do so may result in processing delays. If you believe the information identified below is incorrect, please contact the Office of Product Evaluation and Quality (OPEQ) submission support at (301) 796-5640 or OPEQSubmissionSupport@fda.hhs.gov.

Submission Number: K212224

Received: 7/16/2021

Applicant: Imperative Care Inc.

Device: TracStar Large Distal Platform (LDP) Catheter, Zoom 88 Large Distal Platform (LDP) Catheter

We will notify you when the review of this document 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



Food and Drug Administration
CDRH/OPEQ/OHTV/DHTVA
WO66 RM4276
10903 New Hampshire Ave
Silver Spring, MD 20993-0002
301-796-5613

Premarket Notification 510(k) Review

Date: September 9, 2021

Reviewer: Leigh Anderson

Subject: Special 510(k)# K212224/S001

Applicant: Imperative Care Inc.

Contact Name: Kristin Ellis

Correspondent Firm: Imperative Care Inc.

Received Date: September 2, 2021

Pro Code(s): QJP **Class:** II **Reg #:** 870.1250

Pro Code(s): DQY **Class:** II **Reg #:** 870.1250

Device Trade Name: TracStar LDP Large Distal Platform, Zoom 88 Large Distal Platform

Contact Title: Regulatory Affairs Manager

Phone: (408) 857-0934 **Email:** kellis@imperativecare.com

Due Date: October 2, 2021

Reg Name: Percutaneous Catheter

Reg Name: Percutaneous catheter

Predicate Devices:

Submission #	Pro Code	Device Trade Name	Applicant
K203764	QJP,	TracStar Large Distal Platform,	Imperative Care Inc.
	DQY	ZOOM 88 Large Distal Platform,	
		ZOOM 88-T Large Distal Platform	

(b)(5)

(b)(5)

(b)(5)

(b)(5)

(b)(5)

(b)(5)

(b)(5)

(b)(5)

(b)(5)

(b)(5)

(b)(5)

(b)(5)

(b)(5)

(b)(5)

(b)(5)

(b)(5)

(b)(5)

(b)(5)

(b)(5)

(b)(5)

(b)(5)

(b)(5)

(b)(5)

(b)(5)

(b)(5)

Indications for Use

510(k) Number (if known)

K212224

Device Name

TracStar LDP Large Distal Platform

Zoom 88 Large Distal Platform

Indications for Use (Describe)

The TracStar LDP Large Distal Platform is indicated for the introduction of interventional devices into the peripheral, coronary, and neuro vasculature.

The Zoom 88 Large Distal Platform is indicated for the introduction of interventional devices into the peripheral, coronary, and neuro vasculature.

Type of Use (Select one or both, as applicable)

☒ Prescription Use (Part 21 CFR 801 Subpart D)

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

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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

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

The burden time for this collection of information is estimated to average 79 hours 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
PRASStaff@fda.hhs.gov

"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 number."

Good morning Ms. Anderson,

I know you must be very busy but I'm hoping that you can help me to better understand the review process for Special 510(k)s and the impact to the review time with issuance of an Additional Information letter. I reviewed the FDA Guidance Document "FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Goals, Guidance for Industry and Food and Drug Administration Staff" issued on October 2, 2017 and was not able to locate any language which indicates a reset of the review clock to 30 days for Special 510(k)s. The guidance document indicates that the clock stops upon issuance of a request for additional information and starts again upon receipt of the information. Following this guidance, I was under the impression that the review clock would have started back up at day 20 when Document Control received the requested additional information. Any help you can provide in indicating where I missed this information is appreciated for future submissions so that I can correctly advise project teams.

In addition, is it possible that we will be receiving a response sooner than Oct.2? As always, please let me know if there is any additional information we can provide for the review.

I appreciate the time you have already spent reviewing K212224 and answering my earlier questions. Thank you in advance for taking the time to address these additional questions for my understanding.

Kind regards,
Kristin Ellis

Kristin Ellis
Regulatory Affairs Manager



M: +1.408.857.0934
E: kellis@imperativecare.com
imperativecare.com | [LinkedIn](#) | [Twitter](#) | [YouTube](#)

1359 Dell Avenue, Campbell, CA 95008
www.imperativecare.com

From: Anderson, Leigh <Leigh.Anderson@fda.hhs.gov>
Sent: Tuesday, September 14, 2021 1:49 PM
To: Kristin Ellis <kellis@imperativecare.com>
Cc: Nora Hadding <nhadding@imperativecare.com>; K212224@docs.fda.gov
Subject: RE: [EXTERNAL] K212224 Review Status

Dear Ms. Ellis,

Our goal is to complete review of the response within 30 days of receipt, which shows to be October 2, 2021, in our document tracking system.

Regards,

Leigh Anderson
Biomedical Engineer
Neurointerventional Devices Team
DHTSA: Division of Neurosurgical, Neurointerventional and Neurodiagnostic Devices
OHTS: Office of Neurological and Physical Medicine Devices
Office of Product Evaluation and Quality
CDRH | Food and Drug Administration
White Oak, Bldg. 66, Rm. 4276 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-5613
leigh.anderson@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?ID=1712&S=E>

THIS MESSAGE IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review, disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify the sender by e-mail or phone.

From: Kristin Ellis <kellis@imperativecare.com>
Sent: Tuesday, September 14, 2021 12:45 PM
To: Anderson, Leigh <Leigh.Anderson@fda.hhs.gov>
Cc: Nora Hadding <nhadding@imperativecare.com>; K212224@docs.fda.gov
Subject: RE: [EXTERNAL] K212224 Review Status

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Dear Ms. Anderson,

Thank you for the correction of the review clock day. Can you please provide me with the submission timing review goal for this Special 510(k)? This would be helpful for our planning purposes.

Kind regards,

Kristin Ellis

Regulatory Affairs Manager



M: +1.408.857.0934

E: kellis@imperativecare.com

imperativecare.com | [LinkedIn](#) | [Twitter](#) | [YouTube](#)

1359 Dell Avenue, Campbell, CA 95008

www.imperativecare.com

From: Anderson, Leigh <Leigh.Anderson@fda.hhs.gov>

Sent: Tuesday, September 14, 2021 9:22 AM

To: Kristin Ellis <kellis@imperativecare.com>

Cc: Nora Hadding <nhadding@imperativecare.com>; K212224@docs.fda.gov

Subject: RE: [EXTERNAL] K212224 Review Status

Dear Ms. Ellis,

Thank you for your email.

Our review tracking system indicates that today is day 31 of FDA's review clock for K212224. The submission is still under review at this time. If we have additional questions, we will reach out as soon as possible.

Regards,

Leigh Anderson

Biomedical Engineer

Neurointerventional Devices Team

DHTSA: Division of Neurosurgical, Neurointerventional and Neurodiagnostic Devices

OHTS: Office of Neurological and Physical Medicine Devices

Office of Product Evaluation and Quality

CDRH | Food and Drug Administration

White Oak, Bldg. 66, Rm. 4276 | 10903 New Hampshire Avenue | Silver Spring, MD 20993

Ph: 301-796-5613

leigh.anderson@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?ID=1712&S=E>

THIS MESSAGE IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review, disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify the sender by e-mail or phone.

From: Kristin Ellis <kellis@imperativecare.com>

Sent: Tuesday, September 14, 2021 11:48 AM

To: Anderson, Leigh <Leigh.Anderson@fda.hhs.gov>

Cc: Nora Hadding <nhadding@imperativecare.com>

Subject: [EXTERNAL] K212224 Review Status

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Good morning Ms. Anderson,

I hope this email finds you well. I am contacting you with regards to the review status of K212224. With the request for additional information hold and the Labor Day holiday, I am unsure of the review clock day count. I believe the clock is currently at Day 32. Can you please confirm if this is correct or if not, what

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

date is the end of the review cycle?

Additionally, please let me know if there is any further information you require to complete the review.

Kind regards,

.....
Kristin Ellis

Regulatory Affairs Manager



M: +1.408.857.0934

E: kellis@imperativecare.com

imperativecare.com | [LinkedIn](#) | [Twitter](#) | [YouTube](#)

1359 Dell Avenue, Campbell, CA 95008

www.imperativecare.com

Dear Ms. Ellis,

Thank you for your email.

Our review tracking system indicates that today is day 31 of FDA's review clock for K212224. The submission is still under review at this time. If we have additional questions, we will reach out as soon as possible.

Regards,

Leigh Anderson

Biomedical Engineer

Neurointerventional Devices Team

DHT5A: Division of Neurosurgical, Neurointerventional and Neurodiagnostic Devices

OHT5: Office of Neurological and Physical Medicine Devices

Office of Product Evaluation and Quality

CDRH | Food and Drug Administration

White Oak, Bldg. 66, Rm. 4276 | 10903 New Hampshire Avenue | Silver Spring, MD 20993

Ph: 301-796-5613

leigh.anderson@fda.hhs.gov<mailto:leigh.anderson@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?ID=1712&S=E>

THIS MESSAGE IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review, disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify the sender by e-mail or phone.

From: Kristin Ellis <kellis@imperativecare.com>

Sent: Tuesday, September 14, 2021 11:48 AM

To: Anderson, Leigh <Leigh.Anderson@fda.hhs.gov>

Cc: Nora Hadding <nhadding@imperativecare.com>

Subject: [EXTERNAL] K212224 Review Status

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Good morning Ms. Anderson,

I hope this email finds you well. I am contacting you with regards to the review status of K212224. With the request for additional information hold and the Labor Day holiday, I am unsure of the review clock day count. I believe the clock is currently at Day 32. Can you please confirm if this is correct or if not, what date is the end of the review cycle?

Additionally, please let me know if there is any further information you require to complete the review.

Kind regards,

Kristin Ellis

Regulatory Affairs Manager

[cid:image001.png@01D7A962.DA20C9B0]

M: +1.408.857.0934

E: kellis@imperativecare.com<<mailto:kellis@imperativecare.com>>

[imperativecare.com](http://www.imperativecare.com/)<<http://www.imperativecare.com/>> |

LinkedIn<<https://www.linkedin.com/company/imperativecare/>> |

Twitter<https://twitter.com/imperative_care> |

YouTube<<https://www.youtube.com/channel/UCOXtDHTSq28ZgSHkgtwPhyA>>

1359 Dell Avenue, Campbell, CA 95008

www.imperativecare.com<<http://www.imperativecare.com/>>

510(k) Summary

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

Dear Ms. Ellis,

Thank you for your quick review and reply. We will use the latest versions I sent by email at this point moving forward.

If we have additional questions, we will reach out to you.

Regards,

Leigh Anderson
Biomedical Engineer
Neurointerventional Devices Team
DHT5A: Division of Neurosurgical, Neurointerventional and Neurodiagnostic Devices
OHT5: Office of Neurological and Physical Medicine Devices
Office of Product Evaluation and Quality
CDRH | Food and Drug Administration
White Oak, Bldg. 66, Rm. 4276 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-5613
leigh.anderson@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?ID=1712&S=E>

THIS MESSAGE IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review, disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify the sender by e-mail or phone.

From: Kristin Ellis <kellis@imperativecare.com>
Sent: Thursday, September 9, 2021 5:19 PM
To: Anderson, Leigh <Leigh.Anderson@fda.hhs.gov>
Cc: K212224@docs.fda.gov
Subject: [EXTERNAL] RE: K212224 - Interactive Request

(b)(4)

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Dear Ms. Anderson,

(b)(4)

Kind regards,

Kristin Ellis
Regulatory Affairs Manager



M: +1.408.857.0934
E: kellis@imperativecare.com
imperativecare.com | [LinkedIn](#) | [Twitter](#) | [YouTube](#)
1359 Deli Avenue, Campbell, CA 95008
www.imperativecare.com

From: Anderson, Leigh <Leigh.Anderson@fda.hhs.gov>
Sent: Thursday, September 9, 2021 2:11 PM
To: Kristin Ellis <kellis@imperativecare.com>
Cc: K212224@docs.fda.gov
Subject: K212224 - Interactive Request

(b)(4)

Dear Ms. Ellis,

(b)(4)

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

(b)(4)

Regards,

Leigh Anderson
Biomedical Engineer
Neurointerventional Devices Team
DHT5A: Division of Neurosurgical, Neurointerventional and Neurodiagnostic Devices
OHT5: Office of Neurological and Physical Medicine Devices
Office of Product Evaluation and Quality
CDRH | Food and Drug Administration
White Oak, Bldg. 66, Rm. 4276 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-5613
leigh.anderson@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?ID=1712&S=E>

THIS MESSAGE IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review, disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify the sender by e-mail or phone.

September 1, 2021

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center — W066-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Attn: Leigh Anderson, Biomedical Engineer/Premarket Reviewer

RE: Special 510(k) K212224 — Response to FDA Deficiency List Dated August 4, 2021
for the Imperative Care Large Distal Platform Catheters

Dear Ms. Anderson,

Imperative Care Inc. is submitting one electronic copy (eCopy) of this response to the FDA Deficiency List for the Imperative Care Large Distal Platform Catheters Special 510(k) K212224 received on August 4, 2021. The e-copy was prepared in accordance with CDRH's electronic copy program.

The questions and requests from the list have been included on the following pages in bold print, followed by Imperative Care's response.

The existence of this response is confidential, and the protection afforded to such confidential information by 21 CFR 807.95(b), 18 USC 1905, 21 USC 331(i), 5 USC 552, and other applicable laws is hereby claimed.

Your consideration of these responses is very much appreciated. Should you have any additional questions or require further information, please contact me at (408) 857 - 0934 or via email at kellis@imperativecare.com.

In my absence, please do not hesitate to contact Nora Hadding, Senior Vice President, Regulatory Affairs, Quality Assurance, and Clinical Affairs at **(b)(6)** or via email at nhadding@imperativecare.com.

Sincerely,

(b)(6)

Kristin Ellis - Regulatory Affairs Manager - Imperative Care Inc.

Cc: Nora Hadding - SVP, Regulatory Affairs, Quality Assurance, Clinical Affairs - Imperative Care Inc.

Confidential

Page 1 of 13

K212224 – Deficiency Response, Imperative Care Large Distal Platform Catheters

List of Attachments

(b)(4)

K212224 – Deficiency Response, Imperative Care Large Distal Platform Catheters

Major Deficiency List

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

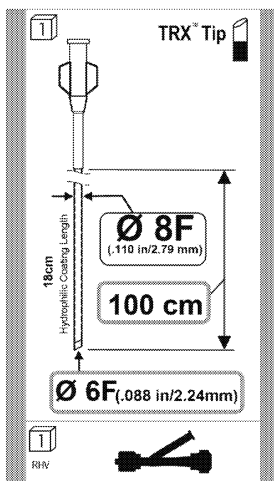
K212224 – Deficiency Response, Imperative Care Large Distal Platform Catheters

Minor Deficiency

(b)(4)

(b)(4)

Records processed under FOIA Request 2023-10349; Released by CDRH on 09-19-2024

Imperative
CARE**Zoom™ 88**
LARGE DISTAL PLATFORM**REF** ICTC088100**LOT** 000000

2018-08-15

**STERILE** 

Attention - See instructions for use for safety information and symbols glossary

R_x Only Prescription only - U.S. Federal Law restricts this device to use by or on the order of a physician

REF ICTC088100 **LOT** 000000

(P1) 0 0512212 03035 1 (17) 180815 (19) 000000

Imperative Care, Inc. ZOOM™ 88 8F 088 LDP, 100 cm

REF ICTC088100 **LOT** 000000

(P1) 0 0512212 03035 1 (17) 180815 (19) 000000

Imperative Care, Inc. ZOOM™ 88 6F 088 LDP, 100 cm

REF ICTC088100 **LOT** 000000

(P1) 0 0512212 03035 1 (17) 180815 (19) 000000

Imperative Care, Inc. ZOOM™ 88 6F 088 LDP, 100 cm

IMPERATIVE CARE, INC.
1359 Dell Avenue
Campbell CA 95008 U.S.A.
~1.408.502.7548

© 2020 Imperative Care, Inc. All Rights Reserved

P-15000324-01

(b)(4)



U.S. FOOD & DRUG
ADMINISTRATION

September 20, 2021

Imperative Care, Inc.
Kristin Ellis
Regulatory Affairs Manager
1359 Dell Avenue
Campbell, California 95008

Re: K212224

Trade/Device Name: TracStar LDP Large Distal Platform; Zoom 88 Large Distal Platform
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: QJP, DQY
Dated: September 1, 2021
Received: September 2, 2021

Dear Kristin Ellis:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm> identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part

801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see <https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products>); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance>) and CDRH Learn (<https://www.fda.gov/training-and-continuing-education/cdrh-learn>). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice>) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,


Naira Muradyan -S

Naira Muradyan, Ph.D.
Assistant Director
DHT5A: Division of Neurosurgical,
Neurointerventional
and Neurodiagnostic Devices
OHT5: Office of Neurological
and Physical Medicine Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K212224

Device Name

TracStar LDP Large Distal Platform

Zoom 88 Large Distal Platform

Indications for Use (Describe)

The TracStar LDP Large Distal Platform is indicated for the introduction of interventional devices into the peripheral, coronary, and neuro vasculature.

The Zoom 88 Large Distal Platform is indicated for the introduction of interventional devices into the peripheral, coronary, and neuro vasculature.

Type of Use (Select one or both, as applicable)

☒ Prescription Use (Part 21 CFR 801 Subpart D)

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

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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

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

The burden time for this collection of information is estimated to average 79 hours 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
PRASStaff@fda.hhs.gov

"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 number."

510(k) Summary

A. Submitter Information

Submitter's Name: Imperative Care, Inc.
Address: 1359 Dell Avenue
Campbell, CA 95008
Contact Person: Kristin Ellis
Telephone: 408-857-0934
Email: kellis@imperativecare.com
Date of Preparation: September 1, 2021

B. Subject Device

Proprietary Names: TracStar™ LDP Large Distal Platform
Zoom™ 88 Large Distal Platform
Common/Usual Name: Guide Catheter
Classification Name: Catheter, Percutaneous, Neurovasculature
Product Code: QJP
DQY
Regulation: 21 CFR 870.1250

C. Predicate Device(s)

Proprietary Name: TracStar™ Large Distal Platform
ZOOM™ 88 Large Distal Platform
ZOOM™ 88-T Large Distal Platform
Common/Usual Name: Guide Catheter
Classification Name: Catheter, Percutaneous, Neurovasculature
Product Code: QJP, DQY
Regulation: 21 CFR. 870.1250
Manufacturer: Imperative Care, Inc.
510(k): K203764

Proprietary Name: EagleRay Long Sheath
EagleRay Access Catheter
Common/Usual Name: Guide Catheter
Classification Name: Catheter, Percutaneous
Product Code: DQY
Regulation: 21 CFR. 870.1250
Manufacturer: Imperative Care Inc.
510(k): K180169

D. Device Description:

The Imperative Care Large Distal Platform (LDP) Catheters include the TracStar™ LDP Large Distal Platform and Zoom™ 88 Large Distal Platform. The LDP Catheters are 0.038" diameter or smaller guidewire compatible single lumen guide catheters that provide

access to peripheral, coronary and neuro vasculature. The catheters are comprised of a hollow cylindrical tube bonded at the proximal end to a standard luer fitting. The wall of the tube is constructed using a combination of metal coils/braids and medical grade polymers. The distal section of each catheter has a hydrophilic coating to enhance tracking through tortuous vasculature. An angled distal soft tip facilitates smooth tracking past vessel branches. A radiopaque marker provides visual confirmation of the distal tip location under fluoroscopy. LDP Catheters have an inner diameter of 0.088" (6F compatible), and a maximum outer diameter of 0.110". The LDP guide catheters are packaged with a rotating hemostasis valve (RHV) that is attached to the proximal luer to help maintain hemostasis.

Accessory devices required, but not supplied include:

- Guidewires
- Support/diagnostic catheters
- Introducer sheaths

E. Indications for Use:

The TracStar LDP Large Distal Platform is indicated for the introduction of interventional devices into the peripheral, coronary, and neuro vasculature.

The Zoom 88 Large Distal Platform is indicated for the introduction of interventional devices into the peripheral, coronary, and neuro vasculature.

F. Principles of Operation:

The LDP Catheters may be used with support catheters to assist in accessing the target vasculature. During use, the male luer of the RHV is attached to the proximal luer of the LDP Catheter to create a continuous lumen through the catheter and to the RHV ports. The female luer is typically connected to a saline drip line while the LDP Catheter is advanced through the vasculature. Use of the LDP Catheter relies on standard percutaneous interventional techniques, including access site preparation, introducing the catheter portion of the device, advancing the catheter under fluoroscopy, withdrawing the catheter, and closing the access site.

G. Predicate Comparison:

The predicate devices are the Imperative Care LDP Catheters cleared under K203764 and K180169. The predicate and subject devices share the same intended use, basic technological characteristics, and the same performance characteristics, demonstrated through bench and

laboratory testing as shown in **Table 1**. Modifications include dimensional updates, additional axial and radial reinforcements, and manufacturing process improvements.

Table 1: Comparison of Subject and Predicate Devices

Device Attribute	Subject device	Predicate devices	
FDA Product Classification	Class II, QJP and DQY, 21 CFR 870.1250	Class II, QJP and DQY, 21 CFR 870.1250	Class II, DQY, 21 CFR 870.1250
Product Name	TracStar LDP Large Distal Platform Zoom 88 Large Distal Platform	TracStar Large Distal Platform ZOOM 88 Large Distal Platform ZOOM 88-T Large Distal Platform	EagleRay Long Sheath EagleRay Access Catheter
510(k) Number	K212224	K203764	K180169
Indications for Use	The TracStar LDP Large Distal Platform is indicated for the introduction of interventional devices into the peripheral, coronary, and neuro vasculature. The Zoom 88 Large Distal Platform is indicated for the introduction of interventional devices into the peripheral, coronary, and neuro vasculature.	The TracStar Large Distal Platform is indicated for the introduction of interventional devices into the peripheral, coronary, and neuro vasculature. The ZOOM 88 and ZOOM 88-T Large Distal Platform are indicated for the introduction of interventional devices into the peripheral, coronary, and neuro vasculature.	The EagleRay Long Sheath and EagleRay Access Catheter are indicated for the introduction of interventional devices into the peripheral, coronary, and neuro vasculature.
Condition Supplied	Sterile and Single Use	Same	Same
Sterilization Method	Ethylene Oxide (EtO), SAL 10 ⁻⁶	Same	Same
Inner Diameter (Distal)	0.088"	Same	Same
Outer Diameter (Distal)	0.106"	Same	Same
Inner Diameter (Proximal)	0.088"	Same	Same
Outer Diameter (Proximal)	0.110"	Same	Same

Device Attribute	Subject device	Predicate device(s)	
Effective Length	80 - 110cm	Same	Same
Tip Design	Beveled distal edge, soft, flexible, atraumatic tip	Same	Same
Distal Catheter Shaft	Additional polymer reinforcement	Reinforced with metals and polymers	Reinforced with metals and polymers
Proximal Catheter Shaft	Additional radial reinforcement	Reinforced with metals and polymers	Reinforced with metals and polymers
Coating	Hydrophilic coating	Same	Same
Materials	Commonly used medical grade plastics & metals with hydrophilic coating	Same	Same
Packaged Accessories	Rotating Hemostasis Valve (RHV)	Same	Same
Packaging Configuration	The catheters are placed in a protective polyethylene tube, mounted with accessory RHV onto a polyethylene packaging card, placed into a pouch, sealed and labeled. The sealed pouch and IFU are placed in a labeled shelf carton box.	Same	Same

H. Performance Data Supporting Substantial Equivalence:

Bench and Laboratory (in-vitro) testing was completed to evaluate the differences between the subject LDP Catheters and predicate LDP Catheters. Performance specifications and test methods were based primarily on catheter performance standard ISO 10555-1 and a summary of the evaluated performance tests and specifications is presented in **Table 2**.

The test results were reviewed and found to demonstrate that the differences between the subject LDP Catheters and predicate LDP Catheters do not significantly impact any performance parameters that would negatively affect the safety or effectiveness of the subject LDP Catheters.

Table 2: Tests and Performance Specifications

Test Attribute	Specification	Results
Delivery, Compatibility, and Retraction (Trackability)	The catheter shall be able to be delivered, deployed, and retracted per the IFU within a simulated neurological model without incurring any damage to the catheter.	Pass
Flexibility and Kink Resistance	There shall be no kinking of shaft (permanent deformation) after simulated use.	Pass
Compatibility with other Devices (external)	The catheters shall be able to be delivered through the minimum introducer sheath or guide catheter size indicated in the product labeling.	Pass
Guidewire Compatibility	The catheters shall be able to be delivered over the maximum size guidewire indicated in the product labeling.	Pass
Interventional Device Compatibility (internal)	The catheters shall be able to accommodate other interventional devices (e.g., support catheter, diagnostic catheter) up to the maximum size indicated in the product labeling.	Pass
Luer Compatibility	Devices and accessories shall be compatible with standard syringe luer fittings per ISO 80369-7.	Pass
Accessory Compatibility	Devices shall be compatible with an RHV.	Pass
Catheter Bond Strength	The catheter shall have sufficient bond strengths to remain intact throughout a procedure.	Pass
Freedom from Leakage – positive pressure	No liquid leakage from the hub or catheter shaft at 46psi for 30 seconds	Pass
Freedom from Leakage – negative pressure	No air leakage into a 20cc syringe when vacuum pulled for 15 seconds.	Pass
Dynamic Burst Pressure	Catheter does not burst under pressures that could be seen when performing contrast injections with a standard 10cc syringe.	Pass
Static Burst Pressure	Catheter does not burst under pressures that could be seen when performing contrast injections with a standard 10cc syringe.	Pass

Test Attribute	Specification	Results
Catheter Torque Strength	With the catheter tip held in a static position, there shall be no separation of any portion of the catheter when rotated at the hub at least two (2) full rotations (720 degrees).	Pass
Kink Resistance	There shall be no kinking of the catheter shaft (permanent deformation) after wrapping around anatomically relevant bend radii.	Pass
Pushability	The proximal shaft of the catheters shall have sufficient stiffness that the user can easily push the catheter to the target anatomy without buckling.	Pass
Access Force	Catheters shall not require excessive force to safely navigate and track to the target anatomy.	Pass

I. Biocompatibility Testing:

There are no changes to patient contacting materials compared to the predicate device. Therefore, the original testing on the predicate devices applies to the subject devices and additional biocompatibility testing was not required.

J. Sterilization:

The LDP Catheters are sterilized using a validated EtO process with a sterility assurance level of 1×10^{-6} validated per the overkill method in accordance with ISO 11135, "Sterilization Of Health-Care Products - Ethylene Oxide - Requirements For The Development, Validation And Routine Control Of A Sterilization Process For Medical Devices".

K. Shelf Life and Packaging:

Accelerated aging testing based on ASTM F1980 was conducted to verify packaged device performance. A real time aging equivalent of 13 months was used to support a 1-year shelf life claim. Device performance was verified by functional and performance testing.

There are no changes to packaging compared to the predicate device. Therefore, the original testing on the predicate devices applies to the subject devices and additional packaging validation testing was not required.

L. Conclusions:

Where differences were identified between the subject and predicate devices, a risk assessment was completed to determine if the difference would result in new safety or effectiveness concerns. As appropriate, previous bench and laboratory testing was evaluated for applicability and either the rationale for no impact was documented or verification and validation was repeated as required.

Based on the results of the risk assessments and associated bench and laboratory testing, the subject and predicate devices are substantially equivalent and there are no new safety or effectiveness concerns. The subject device and predicate devices share the same intended use, basic technological characteristics, and performance characteristics.

Good morning Ms. Anderson,

(b)(4)

Kind regards,

Kristin Ellis

Regulatory Affairs Manager



M: +1.408.857.0934

E: kellis@imperativecare.com

imperativecare.com | [LinkedIn](#) | [Twitter](#) | [YouTube](#)

1359 Dell Avenue, Campbell, CA 95008

www.imperativecare.com

From: Anderson, Leigh <Leigh.Anderson@fda.hhs.gov>

Sent: Monday, September 20, 2021 7:05 AM

To: Kristin Ellis <kellis@imperativecare.com>

Cc: K212224@docs.fda.gov

Subject: K212224 510(k) Summary updates

Dear Ms. Ellis,

(b)(4)

Regards,

Leigh Anderson

Biomedical Engineer

Neurointerventional Devices Team

DHTSA: Division of Neurosurgical, Neurointerventional and Neurodiagnostic Devices

OHT5: Office of Neurological and Physical Medicine Devices

Office of Product Evaluation and Quality

CDRH | Food and Drug Administration

White Oak, Bldg. 66, Rm. 4276 | 10903 New Hampshire Avenue | Silver Spring, MD 20993

Ph: 301-796-5613

leigh.anderson@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?ID=1712&S=E>

THIS MESSAGE IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review, disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify the sender by e-mail or phone.

INSTRUCTIONS FOR USE

TracStar LDP™
LARGE DISTAL PLATFORM

Imperative™
CARE

DEVICE DESCRIPTION

The TracStar LDP™ Large Distal Platform™ (TracStar LDP) is a single lumen, braid and coil reinforced, variable stiffness catheter with a radiopaque marker and a lubricious hydrophilic coating on the distal 14 cm portion of the catheter. The TracStar LDP has an outer diameter of 0.110" (2.8 mm) and is offered in working lengths of 95 cm and 105 cm. Additional dimensions are included on the device labels. The TracStar LDP has a luer hub on the proximal end. The TracStar LDP is compatible with 8F or greater introducer sheaths and 0.038" or smaller guidewires. A support catheter may also be used to assist in accessing the target vasculature.

The TracStar LDP is packaged with an accessory Rotating Hemostasis Valve (RHV). The RHV is intended to be attached to the proximal hub of the TracStar LDP and used to control hemostasis during use with other devices.

INDICATIONS FOR USE

The TracStar LDP Large Distal Platform is indicated for the introduction of interventional devices into the peripheral, coronary, and neuro vasculature.

CONTRAINDICATIONS

There are no known contraindications.

WARNINGS

- The TracStar LDP should only be used by physicians who have received appropriate training in interventional techniques and are proficient in using guide sheaths and catheters.
- Extreme caution should be used if it is required that the TracStar LDP be advanced near or through any aneurysms or other vascular malformations.
- The distal portion of the catheter has a lubricious hydrophilic coating and should be hydrated per Step 7 with heparinized saline before inserting the catheter into the patient. Failure to abide by this warning may result in damage to the device coating, which may necessitate intervention or result in serious adverse events.

PRECAUTIONS

- Use prior to the "Use By" date specified on the product package.
- This device is intended for single use only. Do not resterilize or reuse. After use, dispose in accordance with hospital and/or local government policy.
- Do not use kinked or damaged devices. Do not use open or damaged packages.
- Do not use if the labeling is incomplete or illegible.
- Prior to use, ensure that the dimensions (e.g. diameter and length) of the TracStar LDP and accessory/adjunctive devices to be used in the procedure are compatible with each other and appropriate for the target vasculature.

INSTRUCTIONS FOR USE

TracStar LDP™
LARGE DISTAL PLATFORM

Imperative™
CARE

- To avoid the introduction of embolic fibers, do not use fabric/cloth/gauze to hydrate or wipe down the catheters. Catheters should be hydrated through short immersion in a bath of heparinized saline.
- Use the TracStar LDP in conjunction with fluoroscopic visualization.

Note: Sufficient shielding, reduced fluoroscopy times, and modified X-ray technical factors should be used when possible to limit patient and physician exposure to X-ray radiation doses.

- Exercise care when manipulating the device through tortuous anatomy. Do not advance or withdraw the TracStar LDP or accessory/adjunctive devices against resistance without careful assessment of the cause under fluoroscopy. If the cause cannot be determined, withdraw all devices as a single unit. Excessive manipulation or torqueing the device against resistance may result in damage to the vasculature or the device.
- Precautions to prevent or reduce clotting should be taken when any catheter is used in the vascular system. The use of systematic heparinization and heparinized sterile solution should be considered.
- Maintain a constant infusion of an appropriate flush solution. If using a heparinized flush solution, care should be taken to account for the additional heparin being administered via the flush solution. Failure to do so can result in coagulopathy and excessive bleeding at the access site.
- If flow through the device becomes restricted, do not attempt to clear the lumen by infusion. Remove and replace the device.
- Use of an introducer sheath is necessary to introduce the TracStar LDP into the patient's vasculature. Attempting to introduce the catheter without this introducer can result in kinking or other damage to the device.
- Hemostasis valves should be appropriately used throughout the procedure to minimize blood loss. Monitoring of intra-procedural blood loss throughout the procedure should also be performed to ensure that appropriate management may be instituted as necessary.
- Do not use automated high-pressure contrast injection equipment with the TracStar LDP as it may damage the device.

POTENTIAL ADVERSE EVENTS

Possible complications include, but are not limited to, the following:

- | | |
|--|--|
| • Acute occlusion, Ischemia | • Infection, Sepsis |
| • Unstable angina | • Intracranial hemorrhage |
| • Arrhythmia, including ventricular fibrillation | • Hypotension/Hypertension |
| • Death | • Acute myocardial infarction |
| • Distal embolization | • Infarction/Necrosis |
| • Emboli | • Neurological defects including stroke |
| • False aneurysm formation | • Vessel spasm, thrombosis, dissection, perforation, rupture |
| • Fever | • Drug reactions (e.g. coagulopathy, renal insufficiency/failure, allergic reaction) |
| • Access Site Complications (Hematoma or hemorrhage, sterile inflammation, granulomas) | |

This device is required to be used with fluoroscopy. Potential complications related to angiographic and fluoroscopic X-ray radiation doses include, but are not limited to: alopecia, burns ranging in severity

INSTRUCTIONS FOR USE

TracStar LDP™
LARGE DISTAL PLATFORM

Imperative™
CARE

from skin reddening to ulcers, cataracts, and delayed neoplasia. The probability of occurrence of complications may increase as procedure time and number of procedures increase.

DEVICE PREPARATION AND USE

1. Select an appropriate TracStar LDP based on distance from the access site to the target anatomy. Ensure that the diameter of the TracStar LDP is appropriate for the vasculature.
2. Select an appropriate support catheter based on the dimensions of the TracStar LDP being used, the target vessel, and the surrounding anatomy to help aid in accessing the target vessel.
3. Open the product pouch and place the pouch card into the sterile field. Exercise care when removing the pouch card from the product pouch to prevent damage to the device and accessories.
4. Remove the Rotating Hemostasis Valve (RHV) from the pouch card by removing it from the card tabs before gently lifting the TracStar LDP luer from the pouch card tab and removing the catheter shaft from the protective tubing.
5. Inspect the TracStar LDP and accessories for kinks or other damage. If damage is noted, do not use the device. Replace with an undamaged device.

Use Steps for the TracStar LDP Large Distal Platform

6. Attach the provided RHV to the luer of the TracStar LDP.
7. Hydrate the outer surface of the TracStar LDP and flush the lumen of the catheter and RHV with heparinized saline.

Note: To avoid the introduction of embolic fibers, do not use fabric/cloth/gauze to hydrate or wipe down the catheters. Catheters should be hydrated through short immersion in a bath of heparinized saline.
8. Open the RHV and advance support catheter + guidewire (≤ 0.038 " diameter) into the TracStar LDP until the distal tip of the support catheter is well past the distal tip of the TracStar LDP and then tighten the RHV to secure the support catheter in place. Do not overtighten the RHV as it could deform the support catheter lumen and prevent passage of a guidewire.
9. Gently insert the TracStar LDP/support catheter/guidewire assembly (device assembly) into the 8F or larger introducer sheath.

Note: Follow the introducer sheath manufacturer's instructions for use when performing this step.
10. Under fluoroscopy, advance the device assembly through the introducer sheath and into the patient's vasculature using conventional catheterization techniques.

Note: If injection through the TracStar LDP is necessary, remove the support catheter and guidewire and aspirate the TracStar LDP lumen prior to injection.
11. After gaining access to the desired vessel with the support catheter and guidewire, advance the TracStar LDP over the support catheter to the desired position.
12. Once the desired position is achieved, remove the support catheter and, if necessary, the guidewire.

INSTRUCTIONS FOR USE

TracStar LDP™
LARGE DISTAL PLATFORM

Imperative™
CARE

13. The TracStar LDP can be used as a conduit for other interventional and diagnostic agents to access the target vascular site and distal vessels.

Note: Ensure that the pressure for any fluids being injected through the TracStar LDP does not exceed 300 PSI. Exceeding this value can result in severe vascular trauma.

14. After the procedure has been completed, remove the TracStar LDP through the introducer sheath per standard procedure.
15. Discard the TracStar LDP appropriately per facility procedure.

PACKAGING

The TracStar LDP is placed inside a protective HDPE tube and then secured to a HDPE packaging card. Accessories included in the TracStar LDP packaging include a Rotating Hemostasis Valve (RHV). The packaging card is placed into a Nylon/Tyvek pouch which is thermally sealed to maintain sterility post sterilization.

The TracStar LDP is sterilized using Ethylene Oxide (EtO).

The TracStar LDP will remain sterile unless the pouch is opened, damaged, or the “Use By” date has passed.

MATERIALS

The TracStar LDP is not made with natural rubber latex.

STORAGE AND HANDLING

Keep dry. Keep away from sunlight. Store at room temperature.

SYMBOLS GLOSSARY

Standard Reference: ISO 15223-1 §5.1.5 Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements

Symbol	Definition
	Manufacturer
	Lot number
	Use by
	Attention - See instructions for use for safety information and symbols glossary

INSTRUCTIONS FOR USE

TracStar LDP™
LARGE DISTAL PLATFORM

Imperative™
CARE

	Catalogue number
	Sterilized by ethylene oxide
	Nonpyrogenic
	Prescription only – U.S. Federal Law restricts this device to use by or on the order of a physician
	Do not use if packaging is damaged
	Do not resterilize
	Do not reuse
	Contents (numeral indicates quantity of systems in package)
	Keep away from sunlight
	Keep dry

WARRANTY

Imperative Care, Inc. (“Imperative Care”) warrants that reasonable care has been used in the design and manufacture of this device. This warranty is in lieu of and excludes all other warranties not expressly set forth herein, whether expressed or implied by operation of law or otherwise, including, but not limited to, any implied warranties of merchantability or fitness for a particular use. Handling, storage, cleaning, and sterilization of this device as well as other factors relating to the patient, diagnosis, treatment, surgical procedures, and other matters beyond Imperative Care’s control directly affect the device and the results obtained from its use. Imperative Care’s obligation under this warranty is limited to the replacement of this device and Imperative Care shall not be liable for any incidental, consequential, or special loss, damage, or expense directly or indirectly arising from the use of this device. Imperative Care neither assumes, nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with this device. This warranty is valid only if the device is used in accordance with the manufacturer’s instructions, and the warranty is limited to the original user. Any sale or other transfer or use of the device covered by this warranty to or by a user other than the original user shall cause this warranty to terminate immediately. Imperative Care assumes no liability with respect to devices reused, reprocessed, or resterilized, or serviced, repaired or modified by any party.

INSTRUCTIONS FOR USE

TracStarLDP™
LARGE DISTAL PLATFORM

Imperative™
CARE

other than the original manufacturer, and makes no warranties, expressed or implied, including but not limited to merchantability or fitness for intended use, with respect to such devices.



IMPERATIVE CARE, INC.
1359 Dell Avenue
Campbell, CA 95008 U.S.A.
+1.408.502.7548

© 2020 Imperative Care, Inc. All Rights Reserved.

Records processed under FOIA Request 2023-10349; Released by CDRH on 09-19-2024

Imperative
CARE

TracStar LDP™
LARGE DISTAL PLATFORM

1 **TRX™ Tip**

14cm Hydrophilic Coating Length

Ø 8F (.110 in/2.79 mm)

80 cm

Ø 6F (.088 in/2.24mm)

1 **RTV**

REF ICAC088080

LOT 000000

2018-08-16


(01) 0 08 2212 0001 3 (17) 150915 (10) 000000

STERILE     

 Attention - See instructions for use for safety information and symbols glossary

Rx Only Prescription only. U.S. Federal Law restricts this device to use by or on the order of a physician.

REF ICAC088390 **LOT** 000000


(01) 0 08 2212 0001 3 (17) 150915 (10) 000000
Imperative Care, Inc. TracStar™ 8F 90R LDP, 80 cm

REF ICAC088090 **LOT** 000000


(01) 0 08 2212 0001 3 (17) 150915 (10) 000000
Imperative Care, Inc. TracStar™ 6F 98R LDP, 80 cm

REF ICAC088080 **LOT** 000000


(01) 0 08 2212 0001 3 (17) 150915 (10) 000000
Imperative Care, Inc. TracStar™ 6R 100 LDP, 80 cm


IMPERATIVE CARE, INC.
1369 Dell Avenue
Campbell CA 95008 U.S.A.
+1 408 502 7548
© 2021 Imperative Care, Inc. All Rights Reserved

IFSC02041-01
(b)(4)

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

Imperative Care, Inc.
Special 510(k)

Large Distal Platform Catheters
TracStar LDP and Zoom 88 LDP



Special 510(k)

for the
Large Distal Platform (LDP) Guide Catheters

(TracStar™ LDP and Zoom™ 88 LDP)

Imperative Care, Inc.
1359 Dell Avenue
Campbell, CA 95008

TABLE OF CONTENTS

MDUFMA Cover Sheet (Form FDA 3601)	Section i
CDRH Cover Sheet (Form FDA 3514)	Section ii
FDA Screening Checklist for a Special 510(k)	Section iii
510(k) Cover Letter	Section iv

Imperative Care, Inc. Special 510(k) Submission

SECTION DESCRIPTION	PAGE
TABLE OF CONTENTS	2
APPENDICES	4
1.0 MEDICAL DEVICE USER FEE COVER SHEET (FORM FDA 3601)	5
2.0 CENTER FOR DEVICES AND RADIOLOGICAL HEALTH (CDRH) PREMARKET REVIEW SUBMISSION COVER SHEET (FORM FDA 3514)	5
3.0 510(K) COVER LETTER	5
4.0 PRIOR SUBMISSIONS	5
5.0 INDICATIONS FOR USE STATEMENT (FORM FDA 3881)	5
6.0 510(K) SUMMARY OR 510(K) STATEMENT	5
7.0 TRUTHFUL AND ACCURACY STATEMENT	5
8.0 CLASS III SUMMARY AND CERTIFICATION	6
9.0 FINANCIAL CERTIFICATION OR DISCLOSURE STATEMENT	6
10.0 GENERAL USE OF CONSENSUS STANDARDS IN PERFORMANCE TESTING	6
11.0 SUMMARY OF DESIGN CONTROL, RISK MANAGEMENT, AND DECLARATION OF CONFORMITY	12
11.1 Design Control Process Summary	12
11.2 Risk Management Process Summary	13
12.0 INTRODUCTION	15
13.0 DEVICE DESCRIPTION	18
13.1 TracStar™ LDP and Zoom™ 88 LDP	18
13.2 (b)(4)	20
13.3 Accessories Required but Not Included (b)(4)	21
13.4 Indications for Use (b)(4)	22
13.5 Principles of Operation (b)(4)	22
13.6 Device Packaging (b)(4)	22
13.7 Key Performance Specifications (b)(4)	23
13.8 Device Components and Materials	25
13.9 Device Names, Model Numbers, Sizes and UDI Numbers	27
14.0 MODIFICATIONS TO THE PREDICATE DEVICE	28
15.0 SUBSTANTIAL EQUIVALENCE DISCUSSION	39
15.1 Indications for Use	39
15.2 Comparison of Technological Characteristics and Performance Specifications	39
15.3 Substantial Equivalence Conclusions	50
15.4 510(k) Decision Making Flow Chart	51
16.0 LABELING	53
16.1 Instructions for Use (IFU)	53

16.2	Product Labels	53
17.0	STERILIZATION AND SHELF LIFE	55
17.1	Sterilization (b)(4)	55
17.2	(b)(4)	55
17.3	(b)(4)	56
17.4	(b)(4)	56
17.4.1	(b)(4)	56
17.4.2	(b)(4)	57
17.4.3	(b)(4)	57
17.4.4	(b)(4)	58
17.4.5	(b)(4)	58
17.4.6	(b)(4)	59
17.5	(b)(4)	59
17.6	(b)(4)	60
17.7	(b)(4)	60
18.0	BIOCOMPATIBILITY	61
19.0	SOFTWARE	64
20.0	ELECTROMAGNETIC COMPATIBILITY AND ELECTRICAL SAFETY	64
21.0	PERFORMANCE TESTING – BENCH	64
21.1	Sample Size Selection	64
21.2	(b)(4)	66
21.3	Bench Testing Overall Test Summary Results	66
21.4	(b)(4)	90
21.5	(b)(4)	91
22.0	PERFORMANCE TESTING – ANIMAL	92
23.0	PERFORMANCE TESTING - CLINICAL	92

APPENDICES

Appendix Number	Document Title
Appendix 5-1	Indications for Use Statement (Form FDA 3881)
Appendix 6-1	510(k) Summary
Appendix 7-1	Truthful and Accurate Statement
Appendix 11-1	Design Control Declaration of Conformity
Appendix 13-1	Product Specification LDP Catheters, (b)(4)
Appendix 13-2	Engineering Drawing TracStar (b)(4)
Appendix 13-3	Engineering Drawing Zoom 88 (b)(4)
Appendix 16-1	IFU Redlines TracStar (b)(4)
Appendix 16-2	IFU Draft TracStar (b)(4)
Appendix 16-3	IFU Redlines Zoom88 (b)(4)
Appendix 16-4	IFU Draft Zoom 88 (b)(4)
Appendix 16-5	Draft Product Label TracStar LDP 80cm (b)(4)
Appendix 16-6	Draft Product Label TracStar LDP 90cm (b)(4)
Appendix 16-7	Draft Product Label TracStar LDP 95cm (b)(4)
Appendix 16-8	Draft Product Label TracStar LDP 105cm (b)(4)
Appendix 16-9	Draft Product Label Zoom 88 LDP 100cm (b)(4)
Appendix 16-10	Draft Product Label Zoom 88 LDP 100cm (b)(4)
Appendix 16-11	Representative Redline Product Label

1.0 Medical Device User Fee Cover Sheet (Form FDA 3601)

The *Medical Device User Fee Cover Sheet* is provided on Form FDA 3601 as the cover sheet to this Special 510(k) submission.

2.0 Center for Devices and Radiological Health (CDRH) Premarket Review Submission Cover Sheet (Form FDA 3514)

A CDRH Premarket Review Submission Cover Sheet is provided on Form FDA 3514 and follows Form FDA 3601 in this submission. Pages are numbered within each section.

3.0 510(k) Cover Letter

The 510(k) Cover Letter is located following Form FDA 3514 and is formatted in accordance with Appendix A of FDA Guidance for Industry and FDA Staff, The Special 510(k) Program issued September 13, 2019.

4.0 Prior Submissions

The Imperative Care Large Distal Platform (LDP) Catheters (TracStar and Zoom 88) were originally cleared under **K180169** and subsequently cleared under **K203764**. (b)(4)

(b)(4)

5.0 Indications for Use Statement (Form FDA 3881)

An *Indications for Use Statement* is provided on Form FDA 3881 and is in **Appendix 5-1**.

6.0 510(k) Summary or 510(k) Statement

The 510(k) Summary is provided in **Appendix 6-1**.

7.0 Truthful and Accuracy Statement

A signed Premarket Notification Truthful and Accurate Statement is provided in **Appendix 7-1**.

8.0 Class III Summary and Certification

A Class III Summary and Certification is not applicable to this submission, as substantial equivalency is not claimed for, or to, a Class III device.

9.0 Financial Certification or Disclosure Statement

The Financial Certification or Disclosure Statement is not applicable to this application because clinical data is not required to demonstrate substantial equivalence.

10.0 General Use of Consensus Standards in Performance Testing

(b)(4)

Imperative Care, Inc.
Special 510(k)

Large Distal Platform Catheters
TracStar LDP and Zoom 88 LDP

Table 1: Consensus Standards Used in Performance Testing

(b)(4)

CONFIDENTIAL

Page 7 of 92

Imperative Care, Inc.
Special 510(k)

Large Distal Platform Catheters
TracStar LDP and Zoom 88 LDP

(b)(4)

(b)(4)

CONFIDENTIAL

Page 8 of 92

Imperative Care, Inc.
Special 510(k)

Large Distal Platform Catheters
TracStar LDP and Zoom 88 LDP

(b)(4)

CONFIDENTIAL

Page 9 of 92

Imperative Care, Inc.
Special 510(k)

Large Distal Platform Catheters
TracStar LDP and Zoom 88 LDP

(b)(4)

CONFIDENTIAL

Page 10 of 92

Imperative Care, Inc.
Special 510(k)

Large Distal Platform Catheters
TracStar LDP and Zoom 88 LDP

(b)(4)

CONFIDENTIAL

Page 11 of 92

11.0 Summary of Design Control, Risk Management, and Declaration of Conformity

11.1 Design Control Process Summary

(b)(4)

(b)(4)

11.2 Risk Management Process Summary

(b)(4)

(b)(4)

The results of the risk analysis documented in (b)(4) indicates that the potential benefits associated with the use of the modified TracStar LDP and Zoom 88 LDP Catheters outweigh the potential risks associated with use of the devices under their intended use and

Imperative Care, Inc.
Special 510(k)

Large Distal Platform Catheters
TracStar LDP and Zoom 88 LDP

support that the modified TracStar LDP and Zoom 88 LDP Catheters are substantially equivalent to the predicate TracStar LDP and Zoom 88 LDP Catheters. A signed Design Control Declaration of Conformity is provided in **Appendix 11-1**.

12.0 Introduction

In compliance with Section 510(k) of the 1976 Medical Device Amendments to the Federal Food, Drug and Cosmetic Act, Imperative Care, Inc. is notifying the Food and Drug Administration of our intent to introduce for commercial distribution into interstate commerce modifications to the Imperative Care Large Distal Platform Catheters, (“TracStar LDP” and “Zoom 88 LDP”) recently cleared under **K203764** and originally cleared under **K180169** as the EagleRay Long Sheath. Imperative Care, Inc. is the manufacturer of the TracStar LDP and Zoom 88 LDP.

Table 2: Predicate Device Listing

510(k) Number	Tradename	Model Number	Size (ID x Working Length)
K180169	EagleRay Long Sheath	ICLS088110	0.088”x110cm
		ICLS088100	0.088”x100cm
		ICLS088090	0.088”x90cm
		ICLS088080	0.088”x80cm
K203764	Zoom 88 Large Distal Platform	ICDC088110	0.088”x110cm
		ICDC088100	0.088”x100cm
	Zoom 88-T Large Distal Platform	ICDC088110T	0.088”x110cm
		ICDC088100T	0.088”x100cm
	TracStar Large Distal Platform	ICDC088105	0.088”x105cm
		ICDC088095	0.088”x95cm
		ICDC088090	0.088”x90cm
		ICDC088080	0.088”x80cm

(b)(4)**(b)(4)**

. Performance data was used to evaluate the modifications of the subject devices. There are well-established methods to evaluate the changes and the data can be reviewed and summarized in a risk analysis format. Therefore, review of the modifications to the subject devices is appropriate via the Special 510(k) Program.

Imperative Care has demonstrated through design verification testing that the risks associated with the modifications to the subject TracStar LDP and Zoom 88 LDP are fully mitigated and that the subject devices are as safe and effective as the predicate devices. The differences between the predicate and subject devices do not raise different questions of safety and

effectiveness. Therefore, the subject devices can be considered substantially equivalent to the predicate devices.

Table 3 provides information specified in 21 CFR 807.87.

Imperative Care, Inc.
Special 510(k)

Large Distal Platform Catheters
TracStar LDP and Zoom 88 LDP

Table 3: Required Information

Device Trade or Proprietary Name:	TracStar LDP, Zoom 88 LDP
Device Common or Usual or Classification Name:	Percutaneous Catheter
Establishment Registration Number:	3014590708
Device Classification:	Class II
Classification Panel:	Neurology
Regulation Number per 21 CFR:	870.1250
Product Code:	DQY, QJP
Reason for 510(k):	Modified device
Prior submissions for the same device:	N/A – There are no prior submissions for the subject device.
Prior approval/clearance for components or accessories:	Imperative Care Large Distal Platform (LDP) Catheters [K203764] EagleRay Long Sheath [K180169]
Action taken to comply with Section 514 of the Act for Performance Standards:	No performance standards are referenced under FDA product code DQY or QJP.
Proposed Labels, Labeling and Advertisements:	Section 16.0 and Appendix 16
For Class III Devices Only, a Class III Summary and Class III Certification:	N/A
Device Photographs/ Drawings:	Section 13.0 and Appendix 13
Statement indicating the device is similar and/or different from other products of comparable type in commercial distribution and data to support the statement:	Section 15.0
Supporting data to show consequences and effects the modification has on the safety and effectiveness of the device:	Section 21.0

13.0 Device Description

13.1 TracStar™ LDP and Zoom™ 88 LDP

The Imperative Care Inc. Large Distal Platform (LDP) Catheters are indicated for access to the peripheral, coronary, and neuro vasculature. The LDP Catheters include the TracStar LDP and Zoom 88 LDP Catheters. LDP Catheters are single lumen, variable stiffness catheters with an 0.088” inner diameter (ID), an 0.110” maximum outer diameter (OD), have an angled distal tip (**Figure 1**), and are bonded to a standard luer hub on the proximal end. The LDP Catheters are constructed with medical grade polymers and metal coils/braids and are compatible with 8Fr introducer sheaths and ≤ 0.038 ” guidewires. The distal section of each catheter has a hydrophilic coating (**Figure 2**) to enhance tracking through tortuous vasculature. The distal tip also has a radiopaque marker to provide the user with clear visual confirmation of the distal tip location under fluoroscopy.

(b)(4)

(b)(4)

Figure 2: LDP Catheter Diagram

Imperative Care, Inc.
Special 510(k)

Large Distal Platform Catheters
TracStar LDP and Zoom 88 LDP

(b)(4)

(b)(4)

TracStar LDP Catheters are available in nominal usable (working) lengths of 80cm, 90cm, 95cm, and 105cm. Zoom 88 LDP Catheters are available in 100cm and 110cm lengths. Engineering drawings are provided in **Appendix 13**.

(b)(4)

(b)(4)

13.3 Accessories Required but Not Included (b)(4)

(b)(4) the adjunctive devices and supplies listed below are intended to be used with the LDP Catheters but are not packaged with the LDP Catheters. All of these adjunctive devices and supplies are also commonly used with the predicate devices and are not manufactured by Imperative Care. Accessory information is provided in **Table 4**.

- Guidewires
- Support/diagnostic catheters
- Introducer sheaths

(b)(4)

Table 4: Accessory Information.

Device Type	Key Criteria for Compatibility	Example Device and Manufacturer	Reference 510(k)	Notes
Guidewires	OD: $\leq 0.038''$	(b)(4)		Device examples and 510(k) numbers are provided as examples only. Not exclusively marketed for use with the LDP Catheters.
Support and Diagnostic Catheters	OD: $\leq$ ID of LDP Catheter			
Guide or Introducer Sheath	ID: $\geq$ OD of LDP Catheter			

13.4 Indications for Use (b)(4)

The TracStar LDP Large Distal Platform is indicated for the introduction of interventional devices into the peripheral, coronary, and neuro vasculature.

The Zoom 88 Large Distal Platform is indicated for the introduction of interventional devices into the peripheral, coronary, and neuro vasculature.

13.5 Principles of Operation (b)(4)

(b)(4)

13.6 Device Packaging (b)(4)

(b)(4)

Table 5: Packaging Material

Component	Material
(b)(4)	

Five LDP Catheter shelf cartons are shipped together in a brown corrugated box as shown in **Figure 6**.

(b)(4)

13.7 Key Performance Specifications (b)(4)

The key performance specifications for the LDP Catheter are listed in **Table 6** and (b)(4) *Access Catheter Product Specification*, provided in **Appendix 13**. The overall test summary results are in **Section 21.0**.

Table 6: Key Performance Specifications (b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

Component	Material	Contact Type
(b)(4)		

13.9 Device Names, Model Numbers, Sizes and UDI Numbers

This submission applies to the Imperative Care Inc. LDP Catheters recently cleared in **K203764** and originally cleared in **K180169**. **Table 8** lists the predicate catheters and their tradenames.

Table 8: Predicate Device Tradenames and Model Numbers

510(k) Number	Tradename	Model Number	Size (ID x Working Length)
K180169	EagleRay Long Sheath	ICLS088110	0.088"x110cm
		ICLS088100	0.088"x100cm
		ICLS088090	0.088"x90cm
		ICLS088080	0.088"x80cm
K203764	Zoom 88 Large Distal Platform	ICDC088110	0.088"x110cm
		ICDC088100	0.088"x100cm
	Zoom 88-T Large Distal Platform	ICDC088110T	0.088"x110cm
		ICDC088100T	0.088"x100cm
	TracStar Large Distal Platform	ICDC088105	0.088"x105cm
		ICDC088095	0.088"x95cm
		ICDC088090	0.088"x90cm
		ICDC088080	0.088"x80cm

All models included in the submission are listed in **Table 9**.

Table 9: Tradenames, Model Numbers, Sizes and UDI Numbers

Product Tradename	Model Number	Size (ID x Working Length)	FDA UDI
Zoom 88 Large Distal Platform (LDP)	ICTC088110	0.088"x110cm	00812212030368
	ICTC088100	0.088"x100cm	00812212030351
TracStar Large Distal Platform (LDP)	ICAC088105	0.088"x105cm	00812212030344
	ICAC088095	0.088"x95cm	00812212030337
	ICAC088090	0.088"x90cm	00812212030320
	ICAC088080	0.088"x80cm	00812212030313

14.0 Modifications to the Predicate Device**(b)(4)****(b)(4)**The modifications are summarized in **Table 10**.**(b)(4)**

(b)(4) A schematic of the differences in the subject and predicate TracStar LDP is provided in **Figure 7**. A schematic of the differences in the subject and predicate Zoom 88 LDP is provided in **Figure 8**.

(b)(4)

(b)(4)

Imperative Care, Inc.
Special 510(k)

Large Distal Platform Catheters
TracStar LDP and Zoom 88 LDP

(b)(4)

Each modification was evaluated individually in accordance with the FDA guidance *Deciding When to Submit a 510(k) for a Change to an Existing Device*, dated October 25, 2017 and per ISO 14971 *Medical devices - Application of risk management to medical devices*.

Imperative Care, Inc.
Special 510(k)

Large Distal Platform Catheters
TracStar LDP and Zoom 88 LDP

Table 11: Design Control Activities Summary of Modifications

(b)(4)

CONFIDENTIAL

Page 32 of 92

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

15.0 Substantial Equivalence Discussion

In accordance with FDA Guidance Document, *The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications 510(k)*, dated July 28, 2014, the subject device is substantially equivalent to the Imperative Care Inc. LDP predicate catheters listed in **Table 12** cleared under K203764.

Table 12: Predicate Device Tradename and Model Numbers

510(k) Number	Tradename	Model Number	Size (ID x Working Length)
K180169	EagleRay Long Sheath	ICLS088110	0.088"x110cm
		ICLS088100	0.088"x100cm
		ICLS088090	0.088"x90cm
		ICLS088080	0.088"x80cm
K203764	Zoom 88 Large Distal Platform	ICDC088110	0.088"x110cm
		ICDC088100	0.088"x100cm
	Zoom 88-T Large Distal Platform	ICDC088110T	0.088"x110cm
		ICDC088100T	0.088"x100cm
	TracStar Large Distal Platform	ICDC088105	0.088"x105cm
		ICDC088095	0.088"x95cm
		ICDC088090	0.088"x90cm
		ICDC088080	0.088"x80cm

15.1 Indications for Use

The modified device has the same intended use as the predicate device.

The TracStar LDP Large Distal Platform is indicated for the introduction of interventional devices into the peripheral, coronary, and neuro vasculature.

The Zoom 88 Large Distal Platform is indicated for the introduction of interventional devices into the peripheral, coronary, and neuro vasculature.

15.2 Comparison of Technological Characteristics and Performance Specifications

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

15.3 Substantial Equivalence Conclusions

All technological characteristics of the modified device are substantially equivalent to the predicate devices including scientific technology, design, blood-tissue contacting materials, shelf life, biocompatibility, and sterilization. The modifications listed herein have no impact on the safety, functionality, or the performance of the cleared LDP Catheters.

Bench and lab testing were conducted as appropriate to evaluate any differences that were identified. The comparison between the subject and predicate devices found that the modified devices are substantially equivalent to the predicate devices, and that there are no new safety or effectiveness concerns. This conclusion is based on the subject and predicate devices sharing the same:

- intended use and indication for use,
- technological characteristics:
 - operating principles,
 - basic catheter design,
 - blood tissue and patient contacting materials,
 - shelf life and sterilization,
 - packaging materials and processes.

(b)(4)

15.4 510(k) Decision Making Flow Chart

(b)(4)

Imperative Care, Inc.
Special 510(k)

Large Distal Platform Catheters
TracStar LDP and Zoom 88 LDP

(b)(4)

16.0 Labeling

16.1 Instructions for Use (IFU)

A copy of the instructions for use (IFU) is included within the product packaging for each catheter. Content covered in the IFU includes:

- Indications for Use
- Warnings
- Precautions
- Potential Complications
- Instructions describing the device use steps

The Indication for Use, warnings, and contraindications have not changed as a result of the minor modifications in this submission. (b)(4)

(b)(4) No significant content changes were made to the Instructions for Use (IFU) or package labels. Changes to the IFUs are summarized in **Table 14** below. Redlined and clean copies of the draft TracStar LDP and Zoom 88 LDP IFUs are provided in **Appendix 16**.

No new or significantly modified risks were created because the IFU continues to provide the same:

- descriptive information about the devices
- indications for use, contraindications, warnings and precautions
 - one storage and handling requirement was moved to the precaution section
- basic use steps

16.2 Product Labels

Copies of the draft product labels for the Zoom 88 and TracStar LDP Catheters are provided in **Appendix 16**. A representative redline copy of the product label is provided in **Appendix 16**.

Table 14: Labeling Modifications

(b)(4)

17.0 Sterilization and Shelf Life

17.1 Sterilization (b)(4)

(b)(4)

(b)(4)

The subject LDP Catheters are sterilized using Ethylene oxide (EO) gas exposure with a sterility assurance level of 10^{-6} . The sterilization process was previously validated per the overkill method described in the FDA recognized consensus standard ISO 11135, “*Sterilization Of Health-Care Products – Ethylene Oxide – Requirements For The Development, Validation And Routine Control Of A Sterilization Process For Medical Devices.*” (b)(4)

(b)(4)

(b)(4)

(b)(4)

Imperative Care, Inc.
Special 510(k)

Large Distal Platform Catheters
TracStar LDP and Zoom 88 LDP

5

(b)(4)

Imperative Care, Inc.
Special 510(k)

Large Distal Platform Catheters
TracStar LDP and Zoom 88 LDP

(b)(4)

Imperative Care, Inc.
Special 510(k)

Large Distal Platform Catheters
TracStar LDP and Zoom 88 LDP

(b)(4)

(b)(4)

(b)(4)

Imperative Care, Inc.
Special 510(k)

Large Distal Platform Catheters
TracStar LDP and Zoom 88 LDP

(b)(4)

(b)(4)

(b)(4)

18.0 Biocompatibility

Biocompatibility testing of all components and materials was conducted in the original submission (**K180169**) of the LDP Catheters pursuant to FDA's guidance document *Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process"*, dated June 16, 2016 and ISO 10993-1, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing".

Per FDA guidance document *Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process"* changes to non-patient contacting components typically do not require biocompatibility testing.

(b)(4)

Imperative Care, Inc.
Special 510(k)

Large Distal Platform Catheters
TracStar LDP and Zoom 88 LDP

(b)(4)

Table 18: Summary of Testing Completed to Confirm Subject Device Biocompatibility

(b)(4)

(b)(4)

19.0 Software

N/A

20.0 Electromagnetic Compatibility and Electrical Safety

N/A

21.0 Performance Testing – Bench

(b)(4)

To ensure that the modified devices continue to meet design requirements and product specifications, verification tests were performed at the device and at the subassembly level in accordance with the applicable guidance documents and/or consensus standards. Completion of all verification and validation activities demonstrated that the modified devices passed the predefined acceptance criteria, met the design and performance specifications and are substantially equivalent to the predicate devices.

21.1 Sample Size Selection

(b)(4)

(b)(4)

(b)(4)

21.3 Bench Testing Overall Test Summary Results

(b)(4)

Table 20: Summary of Supportive Bench Testing

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

Figure 10: Tensile Strength Test Method Fixture

(b)(4)

Imperative Care, Inc.
Special 510(k)

Large Distal Platform Catheters
TracStar LDP and Zoom 88 LDP

(b)(4)

Test results are

summarized in **Table 19**.

22.0 Performance Testing – Animal

Animal data was not required for this submission because the subject device shares (b)(4)

(b)(4)

Complete

copies of animal study reports were provided previously in **K180169**. See Attachment 2 in the Imperative Care Inc. response to deficiencies letter dated July 3, 2018.

23.0 Performance Testing - Clinical

Clinical data was not required for this submission.

Dear Ms. Ellis,

Thank you for reaching out. We have received the response for K212224 and are reviewing the information. If we have any additional questions, we will reach out.

Regards,

Leigh Anderson
Biomedical Engineer
Neurointerventional Devices Team
DHT5A: Division of Neurosurgical, Neurointerventional and Neurodiagnostic Devices
OHT5: Office of Neurological and Physical Medicine Devices
Office of Product Evaluation and Quality
CDRH | Food and Drug Administration
White Oak, Bldg. 66, Rm. 4276 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-5613
leigh.anderson@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?ID=1712&S=E>

THIS MESSAGE IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review, disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify the sender by e-mail or phone.

From: Kristin Ellis <kellis@imperativecare.com>
Sent: Wednesday, September 8, 2021 12:18 PM
To: Anderson, Leigh <Leigh.Anderson@fda.hhs.gov>
Subject: [EXTERNAL] Response to FDA request for additional information for K212224

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Dear Ms. Anderson,

I hope this email finds you well.

The response to FDA's request for additional information for K212224 was submitted last week. Please let me know if you have any further questions or if I can provide anything else to assist in the review of the Special 510(k).

Kind regards,

Kristin Ellis
Regulatory Affairs Manager



M: +1.408.857.0934
E: kellis@imperativecare.com
imperativecare.com | [LinkedIn](#) | [Twitter](#) | [YouTube](#)
1359 Deli Avenue, Campbell, CA 95008
www.imperativecare.com



U.S. FOOD & DRUG
ADMINISTRATION

K212224

Imperative Care Inc.

Trade/Device Name: TracStar Large Distal Platform (LDP) Catheter; Zoom 88 Large Distal Platform (LDP) Catheter

Contact Name: Kristin Ellis

This document is being communicated via e-mail as an attachment. The date on which FDA sent this e-mail is the official date of this correspondence.

We have reviewed your submission K212224 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 K212224 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 <https://www.fda.gov/media/83522/download> for current information on eCopy requirements.

Your response is due within 180 days from the date of this request, which is the hold date plus 180 days. If a complete response is not received in CDRH's Document Control Center by this date, 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.

This request for additional information has undergone supervisory review to ensure that the deficiencies cited are least burdensome and relevant to the marketing decision. Please see the revised guidance "Developing and Responding to Deficiencies in Accordance with the Least Burdensome Provisions" issued

on September 29, 2017 (<https://www.fda.gov/media/71735/download>) for clarification regarding major and minor deficiencies.

MAJOR DEFICIENCY LIST

(b)(4)

(b)(4)

MINOR DEFICIENCY LIST

The Agency has identified a minor deficiency that can be resolved in a straightforward manner, but that need to be addressed to meet regulatory requirements or to prevent potential misbranding or adulteration.

(b)(4)

(b)(4)

FDA is offering a teleconference within 10 calendar days from the date on this letter to address any clarification questions you may have pertaining to the deficiencies. If you are interested in a teleconference, please provide (1) proposed dates and (2) a list of your clarification questions via email at least 48 hours before the teleconference to the lead reviewer assigned to your submission. We would like to emphasize that the purpose of the meeting is to address specific clarification questions. Please note that if the specific clarification questions are not received at least 48 hours before the teleconference, the review team might not be able to provide feedback. The teleconference is not intended for review of new information, test methods or data; these types of questions could be better addressed via a Submission Issue Q-Submission (Q-Sub). For additional information regarding Q-Subs, please refer to the Guidance for Industry and FDA Staff on Medical Devices: Requests for Feedback and Meetings for Medical Device Submissions at <https://www.fda.gov/media/114034/download>.

Least Burdensome (LB) Flag

The LB flag is an approach to allow submitters the opportunity for the informal review by or on behalf of Division management of an issue raised in an FDA request for additional information (i.e., a deficiency letter). The goal of the LB flag is to quickly address FDA requests that submitters do not believe are least burdensome or when submitters believe they are being held to a different standard than their legally marketed predicate device. The LB flag is not intended to clarify deficiencies, is not an appeal under 21 CFR 10.75, and is not intended to provide a review of a proposed response to deficiencies.

If you would like to throw the LB flag, FDA has several criteria that should be met before you submit your request:

- You should have tried to address your concern by discussing it with Division management before attempting to throw the LB flag. This discussion with Division management may take place as part of a teleconference (such as the voluntary teleconference held within 10 days following transmission of an Additional Information letter to clarify deficiencies), email, or a Q-Submission Submission Issue Request.
- Your flag should generally be limited to two topic areas. Topic areas are common premarket review deficiency categories that apply to many device types across multiple reviewing Divisions. Examples of topic areas include biocompatibility, sterility, reprocessing, software, electromagnetic compatibility, wireless, electrical safety, clinical, and non-clinical performance testing.
- If you would like to discuss issues pertaining to more than two topic areas, you should contact OPEQSubmissionSupport@fda.hhs.gov for more information.
- You should throw the LB flag within 60 calendar days of the date that FDA sent the deficiency letter.

Upon meeting the criteria, you should send a short email (e.g., 1-2 page) that includes: 1) a summary of the deficiencies under disagreement, 2) a summary of relevant communications with Division management, and 3) a proposed path forward. The LB flag should be sent to the lead reviewer and their Assistant Director. You should also copy OPEQSubmissionSupport@fda.hhs.gov on your LB flag email request. Within two

business days of your email, your request will be acknowledged by the reviewing Division. If you do not meet the criteria for the LB flag, you will be notified in this acknowledgement email.

Your LB flag should contain sufficient information to determine whether the deficiency letter was not least burdensome, or you are being held to a different standard than your predicate device. FDA may request a phone call with you to discuss your concern further and intends to communicate feedback from Division management on LB flags through email no later than 21 calendar days of their receipt. Please note that the LB flag does not change the deadline for your response to the Document Control Center. If you have any questions, please contact OPEQSubmissionSupport@fda.hhs.gov.



Food and Drug Administration
CDRH/OPEQ/OHTV/DHTVA
WO66 RM4276
10903 New Hampshire Ave
Silver Spring, MD 20993-0002
301-796-5613

Premarket Notification 510(k) Review

Date: August 4, 2021

Reviewer: Leigh Anderson

Subject: Special 510(k)# K212224

Applicant: Imperative Care Inc.

Contact Name: Kristin Ellis

Correspondent Firm: Imperative Care Inc.

Received Date: July 16, 2021

Pro Code(s): QJP **Class:** II **Reg #:** 870.1250

Pro Code(s): DQY **Class:** II **Reg #:** 870.1250

Device Trade Name: TracStar Large Distal Platform (LDP) Catheter, Zoom 88 Large Distal Platform (LDP) Catheter

Contact Title: Regulatory Affairs Manager

Phone: (408) 857-0934 **Email:** kellis@imperativecare.com

Due Date: August 15, 2021

Reg Name: Percutaneous Catheter

Reg Name: Percutaneous catheter

Predicate Devices:

Submission #	Pro Code	Device Trade Name	Applicant
K203764	QJP,	TracStar Large Distal Platform,	Imperative Care Inc.
	DQY	ZOOM 88 Large Distal Platform,	
		ZOOM 88-T Large Distal Platform	

(b)(5)

(b)(5)

(b)(5)

(b)(5)

(b)(5)

(b)(5)

(b)(5)

(b)(5)

(b)(5)

(b)(5)

(b)(5)

(b)(5)

(b)(5)

(b)(5)

(b)(5)

(b)(5)

(b)(5)

(b)(5)

(b)(5)

(b)(5)

(b)(5)

Digital Signature Concurrence Table (Doc ID: 04500.14.05)

This document represents a high-level summary of the Agency's determination on whether the applicant's device is substantially equivalent to a legally marketed predicate device. In determining whether the subject device is substantially equivalent to a predicate device, we carefully considered the relevant regulatory and statutory criteria for Agency decision-making under 21 CFR part 807 and section 513(i) of the Federal Food, Drug and Cosmetic Act (FD&C Act). We considered the burden that may be incurred by the applicant's attempt to follow the premarket notification process. The deficiencies provided in this review, if any, represent the required minimum information necessary to support a substantial equivalence determination. Therefore, we believe that we have considered the least burdensome requirements, under section 513(i)(1)(D) of the FD&C Act, for a 510(k) determination of substantial equivalence.

Reviewer Sign-Off

Leigh B. Anderson -S

Digitally signed by Leigh B.

Anderson -S

Date: 2021.08.04 15:13:31 -04'00'

Dear Ms. Anderson,

Thank you for the correction of the review clock day. Can you please provide me with the submission timing review goal for this Special 510(k)? This would be helpful for our planning purposes.

Kind regards,

.....
Kristin Ellis

Regulatory Affairs Manager



M: +1.408.857.0934

E: kellis@imperativecare.com

imperativecare.com | [LinkedIn](#) | [Twitter](#) | [YouTube](#)

1359 Dell Avenue, Campbell, CA 95008

www.imperativecare.com

From: Anderson, Leigh <Leigh.Anderson@fda.hhs.gov>

Sent: Tuesday, September 14, 2021 9:22 AM

To: Kristin Ellis <kellis@imperativecare.com>

Cc: Nora Hadding <nhadding@imperativecare.com>; K212224@docs.fda.gov

Subject: RE: [EXTERNAL] K212224 Review Status

Dear Ms. Ellis,

Thank you for your email.

Our review tracking system indicates that today is day 31 of FDA's review clock for K212224. The submission is still under review at this time. If we have additional questions, we will reach out as soon as possible.

Regards,

Leigh Anderson

Biomedical Engineer

Neurointerventional Devices Team

DHTSA: Division of Neurosurgical, Neurointerventional and Neurodiagnostic Devices

OHT5: Office of Neurological and Physical Medicine Devices

Office of Product Evaluation and Quality

CDRH | Food and Drug Administration

White Oak, Bldg. 66, Rm. 4276 | 10903 New Hampshire Avenue | Silver Spring, MD 20993

Ph: 301-796-5613

leigh.anderson@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?ID=1712&S=E>

THIS MESSAGE IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review, disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify the sender by e-mail or phone.

From: Kristin Ellis <kellis@imperativecare.com>

Sent: Tuesday, September 14, 2021 11:48 AM

To: Anderson, Leigh <Leigh.Anderson@fda.hhs.gov>

Cc: Nora Hadding <nhadding@imperativecare.com>

Subject: [EXTERNAL] K212224 Review Status

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Good morning Ms. Anderson,

I hope this email finds you well. I am contacting you with regards to the review status of K212224. With the request for additional information hold and the Labor Day holiday, I am unsure of the review clock day count. I believe the clock is currently at Day 32. Can you please confirm if this is correct or if not, what date is the end of the review cycle?

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

Additionally, please let me know if there is any further information you require to complete the review.

Kind regards,

.....
Kristin Ellis

Regulatory Affairs Manager



M: +1.408.857.0934

E: kellis@imperativecare.com

imperativecare.com | [LinkedIn](#) | [Twitter](#) | [YouTube](#)

1359 Dell Avenue, Campbell, CA 95008

www.imperativecare.com

INSTRUCTIONS FOR USE

Zoom™ 88
LARGE DISTAL PLATFORM

Imperative™
CARE

DEVICE DESCRIPTION

The Zoom™ 88 Large Distal Platform™ catheters (Zoom 88) are single lumen, braid and coil reinforced, variable stiffness catheters with a radiopaque marker and a lubricious hydrophilic coating on the distal 18 cm portion of the catheter. The Zoom 88 has an outer diameter of 0.110" (2.8 mm) and is offered in a working length of 110 cm. Additional dimensions are included on the device label. The Zoom 88 has a luer hub on the proximal end. The Zoom 88 is compatible with 8F or greater introducer sheaths and 0.038" or smaller guidewires. A support catheter may also be used to assist in accessing the target vasculature.

The Zoom 88 is packaged with an accessory Rotating Hemostasis Valve (RHV). The RHV is intended to be attached to the proximal hub of the Zoom 88 and used to control hemostasis during use with other devices.

INDICATIONS FOR USE

The Zoom 88 Large Distal Platform is indicated for the introduction of interventional devices into the peripheral, coronary, and neuro vasculature.

CONTRAINDICATIONS

There are no known contraindications.

WARNINGS

- The Zoom 88 should only be used by physicians who have received appropriate training in interventional techniques and are proficient in using guide sheaths and catheters.
- Extreme caution should be used if it is required that the Zoom 88 be advanced near or through any aneurysms or other vascular malformations.
- The distal portion of the catheter has a lubricious hydrophilic coating and should be hydrated per Step 7 with heparinized saline before inserting the catheter into the patient. Failure to abide by this warning may result in damage to the device coating, which may necessitate intervention or result in serious adverse events.

PRECAUTIONS

- Use prior to the "Use By" date specified on the product package.
- This device is intended for single use only. Do not resterilize or reuse. After use, dispose in accordance with hospital and/or local government policy.
- Do not use kinked or damaged devices. Do not use open or damaged packages.
- Do not use if the labeling is incomplete or illegible.
- Prior to use, ensure that the dimensions (e.g. diameter and length) of the Zoom 88 and accessory/adjunctive devices to be used in the procedure are compatible with each other and appropriate for the target vasculature.
- To avoid the introduction of embolic fibers, do not use fabric/cloth/gauze to hydrate or wipe down the catheters. Catheters should be hydrated through short immersion in a bath of heparinized saline.

INSTRUCTIONS FOR USE

Zoom™ 88
LARGE DISTAL PLATFORM

Imperative™
CARE

- Use the Zoom 88 in conjunction with fluoroscopic visualization.

Note: Sufficient shielding, reduced fluoroscopy times, and modified X-ray technical factors should be used when possible to limit patient and physician exposure to X-ray radiation doses.

- Exercise care when manipulating the device through tortuous anatomy. **Do not** advance or withdraw the Zoom 88 or accessory/adjunctive devices against resistance without careful assessment of the cause under fluoroscopy. If the cause cannot be determined, withdraw all devices as a single unit. Excessive manipulation or torquing the device against resistance may result in damage to the vasculature or the device.
- Precautions to prevent or reduce clotting should be taken when any catheter is used in the vascular system. The use of systematic heparinization and heparinized sterile solution should be considered.
- Maintain a constant infusion of an appropriate flush solution. If using a heparinized flush solution, care should be taken to account for the additional heparin being administered via the flush solution. Failure to do so can result in coagulopathy and excessive bleeding at the access site.
- If flow through the device becomes restricted, **do not** attempt to clear the lumen by infusion. Remove and replace the device.
- Use of an introducer sheath is necessary to introduce the Zoom 88 into the patient's vasculature. Attempting to introduce the catheter without this introducer can result in kinking or other damage to the device.
- Hemostasis valves should be appropriately used throughout the procedure to minimize blood loss. Monitoring of intra-procedural blood loss throughout the procedure should also be performed to ensure that appropriate management may be instituted as necessary.
- **Do not** use automated high-pressure contrast injection equipment with the Zoom 88 as it may damage the device.

POTENTIAL ADVERSE EVENTS

Possible complications include, but are not limited to, the following:

- | | |
|--|--|
| • Acute occlusion, Ischemia | • Infection, Sepsis |
| • Unstable angina | • Intracranial hemorrhage |
| • Arrhythmia, including ventricular fibrillation | • Hypotension/Hypertension |
| • Death | • Acute myocardial infarction |
| • Distal embolization | • Infarction/Necrosis |
| • Emboli | • Neurological defects including stroke |
| • False aneurysm formation | • Vessel spasm, thrombosis, dissection, perforation, rupture |
| • Fever | • Drug reactions (e.g. coagulopathy, renal insufficiency/failure, allergic reaction) |
| • Access Site Complications (Hematoma or hemorrhage, sterile inflammation, granulomas) | |

This device is required to be used with fluoroscopy. Potential complications related to angiographic and fluoroscopic X-ray radiation doses include, but are not limited to: alopecia, burns ranging in severity from skin reddening to ulcers, cataracts, and delayed neoplasia. The probability of occurrence of complications may increase as procedure time and number of procedures increase.

INSTRUCTIONS FOR USE

Zoom™ 88
LARGE DISTAL PLATFORM

Imperative™
CARE

DEVICE PREPARATION AND USE

1. Select an appropriate Zoom 88 based on the distance from the access site to the target anatomy. Ensure that the diameter of the Zoom 88 is appropriate for the vasculature.
2. Select an appropriate support catheter based on the dimensions of Zoom 88 being used, the target vessel, and the surrounding anatomy to help aid in accessing the target vessel.
3. Open the product pouch and place the pouch card into the sterile field. Exercise care when removing the pouch card from the product pouch to prevent damage to the device and accessories.
4. Remove the Rotating Hemostasis Valve (RHV) from the pouch card by removing it from the card tabs before gently lifting the Zoom 88 luer from the pouch card tab and removing the catheter shaft from the protective tubing.
5. Inspect the Zoom 88 and accessories for kinks or other damage. If damage is noted, do not use the device. Replace with an undamaged device.

Use Steps for the Zoom 88 Large Distal Platform

6. Attach the provided RHV to the luer of the Zoom 88.
7. Hydrate the outer surface of the Zoom 88 and flush the lumen of the catheter and RHV with heparinized saline.

Note: To avoid the introduction of embolic fibers, do not use fabric/cloth/gauze to hydrate or wipe down the catheters. Catheters should be hydrated through short immersion in a bath of heparinized saline.
8. Open the RHV and advance support catheter + guidewire (≤ 0.038 " diameter) into the Zoom 88 until the distal tip of the support catheter is well past the distal tip of the Zoom 88 and then tighten the RHV to secure the support catheter in place. Do not overtighten the RHV as it could deform the support catheter lumen and prevent passage of a guidewire.
9. Gently insert the Zoom 88/support catheter/guidewire assembly (device assembly) into the 8F or larger introducer sheath.

Note: Follow the introducer sheath manufacturer's instructions for use when performing this step.
10. Under fluoroscopy, advance the device assembly through the introducer sheath and into the patient's vasculature using conventional catheterization techniques.

Note: If injection through the Zoom 88 is necessary, remove the support catheter and guidewire and aspirate the Zoom 88 lumen prior to injection.
11. After gaining access to the desired vessel with the support catheter and guidewire, advance the Zoom 88 over the support catheter to the desired position.
12. Once the desired position is achieved, remove the support catheter and, if necessary, the guidewire.

INSTRUCTIONS FOR USE

Zoom™ 88
LARGE DISTAL PLATFORM

Imperative™
CARE

13. The Zoom 88 can be used as a conduit for other interventional and diagnostic agents to access the target vascular site and distal vessels.

Note: Ensure that the pressure for any fluids being injected through the Zoom 88 does not exceed 300 PSI. Exceeding this value can result in severe vascular trauma.

14. After the procedure has been completed, remove the Zoom 88 through the introducer sheath per standard procedure.
15. Discard the Zoom 88 appropriately per facility procedure.

PACKAGING

The Zoom 88 is placed inside a protective HDPE tube and then secured to a HDPE packaging card. Accessories included in the Zoom 88 packaging include a Rotating Hemostasis Valve (RHV). The packaging card is placed into a Nylon/Tyvek pouch which is thermally sealed to maintain sterility post sterilization.

The Zoom 88 is sterilized using Ethylene Oxide (EtO).

The Zoom 88 will remain sterile unless the pouch is opened, damaged, or the “Use By” date has passed.

MATERIALS

The Zoom 88 is not made with natural rubber latex.

STORAGE AND HANDLING

Keep dry. Keep away from sunlight. Store at room temperature.

SYMBOLS GLOSSARY

Standard Reference: ISO 15223-1 §5.1.5 Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements

Symbol	Definition
	Manufacturer
	Lot number
	Use by
	Attention - See instructions for use for safety information and symbols glossary

INSTRUCTIONS FOR USE

Zoom™ 88
LARGE DISTAL PLATFORM

Imperative™
CARE

	Catalogue number
	Sterilized by ethylene oxide
	Nonpyrogenic
	Prescription only – U.S. Federal Law restricts this device to use by or on the order of a physician
	Do not use if packaging is damaged
	Do not resterilize
	Do not reuse
	Contents (numeral indicates quantity of systems in package)
	Keep away from sunlight
	Keep dry

WARRANTY

Imperative Care, Inc. (“Imperative Care”) warrants that reasonable care has been used in the design and manufacture of this device. This warranty is in lieu of and excludes all other warranties not expressly set forth herein, whether expressed or implied by operation of law or otherwise, including, but not limited to, any implied warranties of merchantability or fitness for a particular use. Handling, storage, cleaning, and sterilization of this device as well as other factors relating to the patient, diagnosis, treatment, surgical procedures, and other matters beyond Imperative Care’s control directly affect the device and the results obtained from its use. Imperative Care’s obligation under this warranty is limited to the replacement of this device and Imperative Care shall not be liable for any incidental, consequential, or special loss, damage, or expense directly or indirectly arising from the use of this device. Imperative Care neither assumes, nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with this device. This warranty is valid only if the device is used in accordance with the manufacturer’s instructions, and the warranty is limited to the original user. Any sale or other transfer or use of the device covered by this warranty to or by a user other than the original user shall cause this warranty to terminate immediately. Imperative Care assumes no liability with respect to devices reused, reprocessed, or resterilized, or serviced, repaired or modified by any party.

INSTRUCTIONS FOR USE

Zoom™ 88
LARGE DISTAL PLATFORM

Imperative™
CARE

other than the original manufacturer, and makes no warranties, expressed or implied, including but not limited to merchantability or fitness for intended use, with respect to such devices.



IMPERATIVE CARE, INC.
1359 Dell Avenue
Campbell CA 95008 U.S.A.
+1.408.502.7548

© 2020 Imperative Care, Inc., All Rights Reserved

Good morning Ms. Anderson,

(b)(4)

Kind regards,

Kristin Ellis

Regulatory Affairs Manager

[cid:image001.png@01D7ADF8.3D7BD7E0]

M: +1.408.857.0934

E: kellis@imperativecare.com<<mailto:kellis@imperativecare.com>>

[imperativecare.com](http://www.imperativecare.com/)<<http://www.imperativecare.com/>> |
[LinkedIn](https://www.linkedin.com/company/imperativecare/)<<https://www.linkedin.com/company/imperativecare/>> |
[Twitter](https://twitter.com/imperative_care)<https://twitter.com/imperative_care> |
[YouTube](https://www.youtube.com/channel/UCOXtDHTSq28ZgSHkgtwPhyA)<<https://www.youtube.com/channel/UCOXtDHTSq28ZgSHkgtwPhyA>>

1359 Dell Avenue, Campbell, CA 95008

www.imperativecare.com<<http://www.imperativecare.com/>>

From: Anderson, Leigh <Leigh.Anderson@fda.hhs.gov>

Sent: Monday, September 20, 2021 7:05 AM

To: Kristin Ellis <kellis@imperativecare.com>

Cc: K212224@docs.fda.gov

Subject: K212224 (b)(4)

Dear Ms. Ellis,

(b)(4)

Regards,

Leigh Anderson

Biomedical Engineer

Neurointerventional Devices Team

DHT5A: Division of Neurosurgical, Neurointerventional and Neurodiagnostic Devices

OHT5: Office of Neurological and Physical Medicine Devices

Office of Product Evaluation and Quality

CDRH | Food and Drug Administration

White Oak, Bldg. 66, Rm. 4276 | 10903 New Hampshire Avenue | Silver Spring, MD 20993

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

Ph: 301-796-5613

leigh.anderson@fda.hhs.gov<mailto:leigh.anderson@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?ID=1712&S=E<https://nam12.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.research.net%2Fs%2Fcdrhcustomerservice%3FID%3D1712%26S%3DE&data=04%7C01%7Ckellis%40imperativecare.com%7Cd7b9db26fc7a46b3d97d08d97c3fccd3%7Cf9bc67a2b9bd4bcc974aec60ef533fdc%7C0%7C0%7C637677436365610163%7CUnknown%7CTWFPbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6IklhaWwiLCJXVCi6Mn0%3D%7C1000&sdata=SaLEvTiPAjPQHAFmoHGnUw4jF7Invq5s6AwSpc878HA%3D&reserved=0>>

THIS MESSAGE IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review, disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify the sender by e-mail or phone.

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

From: Anderson, Leigh
To: Anderson, Leigh
Subject: FW: K212224 ((AINN)) (b)(5)
Date: Wednesday, August 4, 2021 2:57:01 PM
Attachments: K212224.AdditionalInformation (b)(5)
K212224.AdditionalInformation

(b)(5)

From: Muradyan, Naira <Naira.Muradyan@fda.hhs.gov>
Sent: Wednesday, August 4, 2021 2:54 PM
To: Anderson, Leigh <Leigh.Anderson@fda.hhs.gov>
Subject: RE: K212224 ((AINN)) (b)(5)

Thanks again Leigh, (b)(5)
Naira

From: Anderson, Leigh <Leigh.Anderson@fda.hhs.gov>
Sent: Wednesday, August 4, 2021 11:01 AM
To: Muradyan, Naira <Naira.Muradyan@fda.hhs.gov>
Subject: K212224 ((AINN)) (b)(5)

Dear Naira,

(b)(5)

Please let me know if you have any questions.

Thanks,
Leigh

Leigh Anderson

Biomedical Engineer

Neurointerventional Devices Team

DHT5A: Division of Neurosurgical, Neurointerventional and Neurodiagnostic Devices

OHT5: Office of Neurological and Physical Medicine Devices

Office of Product Evaluation and Quality

CDRH | Food and Drug Administration

White Oak, Bldg. 66, Rm. 4276 | 10903 New Hampshire Avenue | Silver Spring, MD 20993

Ph: 301-796-5613

leigh.anderson@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?ID=1712&S=E>



U.S. FOOD & DRUG
ADMINISTRATION

[Build Correspondence](#)

[Convert to PDF](#)

(b)(5)

(b)(5)

(b)(5)

(b)(5)

(b)(5)



[Build Correspondence](#)

[Convert to PDF](#)

(b)(5)

(b)(5)

(b)(5)

(b)(5)

(b)(5)

From: Anderson, Leigh
To: Muradyan, Naira
Subject: FW: [EXTERNAL] RE: K212224 (b)(4)
Date: Monday, September 20, 2021 11:22:00 AM
Attachments: image001.png

Hi Naira,

(b)(4)

Thanks
Leigh

From: Kristin Ellis <kellis@imperativecare.com>
Sent: Monday, September 20, 2021 11:20 AM
To: Anderson, Leigh <Leigh.Anderson@fda.hhs.gov>
Cc: K212224@docs.fda.gov; Nora Hadding <nhadding@imperativecare.com>
Subject: [EXTERNAL] RE: K212224 (b)(4)

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Good morning Ms. Anderson,

(b)(4)

Kind regards,

Kristin Ellis
Regulatory Affairs Manager

Imperative™
CARE

M: +1.408.857.0934
E: kellis@imperativecare.com
imperativecare.com | [LinkedIn](#) | [Twitter](#) | [YouTube](#)

1359 Dell Avenue, Campbell, CA 95008
www.imperativecare.com

From: Anderson, Leigh <Leigh.Anderson@fda.hhs.gov>

Sent: Monday, September 20, 2021 7:05 AM
To: Kristin Ellis <kellis@imperativecare.com>
Cc: K212224@docs.fda.gov
Subject: K212224 (b)(4)

Dear Ms. Ellis,

(b)(4)

Regards,

Leigh Anderson

Biomedical Engineer

Neurointerventional Devices Team

DHT5A: Division of Neurosurgical, Neurointerventional and Neurodiagnostic Devices

OHT5: Office of Neurological and Physical Medicine Devices

Office of Product Evaluation and Quality

CDRH | Food and Drug Administration

White Oak, Bldg. 66, Rm. 4276 | 10903 New Hampshire Avenue | Silver Spring, MD 20993

Ph: 301-796-5613

leigh.anderson@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?ID=1712&S=E>

THIS MESSAGE IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review, disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify the sender by e-mail or phone.

From: Muradyan, Naira
To: Anderson, Leigh
Subject: RE: K212224 ((AINN)) (b)(5)
Date: Wednesday, August 4, 2021 2:54:05 PM
Attachments: K212224.AdditionalInformation (b)(5)

Thanks again Leigh, (b)(5)
Naira

From: Anderson, Leigh <Leigh.Anderson@fda.hhs.gov>
Sent: Wednesday, August 4, 2021 11:01 AM
To: Muradyan, Naira <Naira.Muradyan@fda.hhs.gov>
Subject: K212224 ((AINN)) (b)(5)

Dear Naira,

(b)(5)

Please let me know if you have any questions.

Thanks,
Leigh

Leigh Anderson
Biomedical Engineer

Neurointerventional Devices Team

DHT5A: Division of Neurosurgical, Neurointerventional and Neurodiagnostic Devices

OHT5: Office of Neurological and Physical Medicine Devices

Office of Product Evaluation and Quality

CDRH | Food and Drug Administration

White Oak, Bldg. 66, Rm. 4276 | 10903 New Hampshire Avenue | Silver Spring, MD 20993

Ph: 301-796-5613

leigh.anderson@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?ID=1712&S=E>

From: Anderson, Leigh
To: Muradyan, Naira
Subject: RE: K212224 ((AINN)) (b)(5)
Date: Wednesday, August 4, 2021 3:18:00 PM
Attachments: K212224.AdditionalInformation (b)(5)

Thanks Naira,

(b)(5)

Leigh Anderson

Biomedical Engineer

Neurointerventional Devices Team

DHT5A: Division of Neurosurgical, Neurointerventional and Neurodiagnostic Devices

OHT5: Office of Neurological and Physical Medicine Devices

Office of Product Evaluation and Quality

CDRH | Food and Drug Administration

White Oak, Bldg. 66, Rm. 4276 | 10903 New Hampshire Avenue | Silver Spring, MD 20993

Ph: 301-796-5613

leigh.anderson@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?ID=1712&S=E>

From: Muradyan, Naira <Naira.Muradyan@fda.hhs.gov>

Sent: Wednesday, August 4, 2021 2:54 PM

To: Anderson, Leigh <Leigh.Anderson@fda.hhs.gov>

Subject: RE: K212224 ((AINN)) (b)(5)

Thanks again Leigh, (b)(5)
Naira

From: Anderson, Leigh <Leigh.Anderson@fda.hhs.gov>

Sent: Wednesday, August 4, 2021 11:01 AM

To: Muradyan, Naira <Naira.Muradyan@fda.hhs.gov>

Subject: K212224 ((AINN)) (b)(5)

Dear Naira,

(b)(5)

Please let me know if you have any questions.

Thanks,
Leigh

Leigh Anderson

Biomedical Engineer

Neurointerventional Devices Team

DHT5A: Division of Neurosurgical, Neurointerventional and Neurodiagnostic Devices

OHT5: Office of Neurological and Physical Medicine Devices

Office of Product Evaluation and Quality

CDRH | Food and Drug Administration

White Oak, Bldg. 66, Rm. 4276 | 10903 New Hampshire Avenue | Silver Spring, MD 20993

Ph: 301-796-5613

leigh.anderson@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?ID=1712&S=E>



U.S. FOOD & DRUG
ADMINISTRATION

Build Correspondence

Convert to PDF

K212224

Imperative Care Inc.

Trade/Device Name: TracStar Large Distal Platform (LDP) Catheter; Zoom 88 Large Distal Platform (LDP) Catheter

Contact Name: Kristin Ellis

This document is being communicated via e-mail as an attachment. The date on which FDA sent this e-mail is the official date of this correspondence.

We have reviewed your submission K212224 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 K212224 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 <https://www.fda.gov/media/83522/download> for current information on eCopy requirements.

Your response is due within 180 days from the date of this request, which is the hold date plus 180 days. If a complete response is not received in CDRH's Document Control Center by this date, 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.

This request for additional information has undergone supervisory review to ensure that the deficiencies cited are least burdensome and relevant to the marketing decision. Please see the revised guidance "Developing and Responding to Deficiencies in Accordance with the Least Burdensome Provisions" issued

on September 29, 2017 (<https://www.fda.gov/media/71735/download>) for clarification regarding major and minor deficiencies.

MAJOR DEFICIENCY LIST

The Agency has identified major deficiencies that if not adequately resolved, may preclude a favorable decision on the marketing application.

(b)(4)

(b)(4)

MINOR DEFICIENCY LIST

The Agency has identified a minor deficiency that can be resolved in a straightforward manner, but that need to be addressed to meet regulatory requirements or to prevent potential misbranding or adulteration.

(b)(4)

(b)(4)

Least Burdensome (LB) Flag

The LB flag is an approach to allow submitters the opportunity for the informal review by or on behalf of Division management of an issue raised in an FDA request for additional information (i.e., a deficiency letter). The goal of the LB flag is to quickly address FDA requests that submitters do not believe are least burdensome or when submitters believe they are being held to a different standard than their legally marketed predicate device. The LB flag is not intended to clarify deficiencies, is not an appeal under 21 CFR 10.75, and is not intended to provide a review of a proposed response to deficiencies.

If you would like to throw the LB flag, FDA has several criteria that should be met before you submit your request:

- You should have tried to address your concern by discussing it with Division management before attempting to throw the LB flag. This discussion with Division management may take place as part of a teleconference (such as the voluntary teleconference held within 10 days following transmission of an Additional Information letter to clarify deficiencies), email, or a Q-Submission Submission Issue Request.
- Your flag should generally be limited to two topic areas. Topic areas are common premarket review deficiency categories that apply to many device types across multiple reviewing Divisions. Examples of topic areas include biocompatibility, sterility, reprocessing, software, electromagnetic compatibility, wireless, electrical safety, clinical, and non-clinical performance testing.
- If you would like to discuss issues pertaining to more than two topic areas, you should contact OPEQSubmissionSupport@fda.hhs.gov for more information.
- You should throw the LB flag within 60 calendar days of the date that FDA sent the deficiency letter.

Upon meeting the criteria, you should send a short email (e.g., 1-2 page) that includes: 1) a summary of the deficiencies under disagreement, 2) a summary of relevant communications with Division management, and 3) a proposed path forward. The LB flag should be sent to the lead reviewer and their Assistant Director. You should also copy OPEQSubmissionSupport@fda.hhs.gov on your LB flag email request. Within two

business days of your email, your request will be acknowledged by the reviewing Division. If you do not meet the criteria for the LB flag, you will be notified in this acknowledgement email.

Your LB flag should contain sufficient information to determine whether the deficiency letter was not least burdensome, or you are being held to a different standard than your predicate device. FDA may request a phone call with you to discuss your concern further and intends to communicate feedback from Division management on LB flags through email no later than 21 calendar days of their receipt. Please note that the LB flag does not change the deadline for your response to the Document Control Center. If you have any questions, please contact OPEQSubmissionSupport@fda.hhs.gov.

From: [Anderson, Leigh](#)
To: [Muradyan, Naira](#)
Subject: RE: K212224/S001 ((SESE)) (b)(5)
Date: Monday, September 20, 2021 9:54:00 AM

Thanks Naira. (b)(5)

-leigh

From: Muradyan, Naira <Naira.Muradyan@fda.hhs.gov>

Sent: Monday, September 20, 2021 9:52 AM

To: Anderson, Leigh <Leigh.Anderson@fda.hhs.gov>

Subject: RE: K212224/S001 ((SESE)) (b)(5)

(b)(5)

Thanks

Naira

From: Anderson, Leigh <Leigh.Anderson@fda.hhs.gov>

Sent: Friday, September 10, 2021 9:56 AM

To: Muradyan, Naira <Naira.Muradyan@fda.hhs.gov>

Subject: RE: K212224/S001 ((SESE)) (b)(5)

(b)(5)

Thanks!

Leigh

From: Muradyan, Naira <Naira.Muradyan@fda.hhs.gov>

Sent: Friday, September 10, 2021 7:19 AM

To: Anderson, Leigh <Leigh.Anderson@fda.hhs.gov>

Subject: RE: K212224/S001 ((SESE)) (b)(5)

(b)(5)

Thanks,
Naira

From: Anderson, Leigh <Leigh.Anderson@fda.hhs.gov>

Sent: Thursday, September 9, 2021 8:21 PM

To: Muradyan, Naira <Naira.Muradyan@fda.hhs.gov>

Subject: K212224/S001 ((SESE)) (b)(5)

Dear Naira,

(b)(5)

Please let me know if you have any questions.

Thanks,
Leigh

Leigh Anderson

Biomedical Engineer

Neurointerventional Devices Team

DHT5A: Division of Neurosurgical, Neurointerventional and Neurodiagnostic Devices

OHT5: Office of Neurological and Physical Medicine Devices

Office of Product Evaluation and Quality

CDRH | Food and Drug Administration

White Oak, Bldg. 66, Rm. 4276 | 10903 New Hampshire Avenue | Silver Spring, MD 20993

Ph: 301-796-5613

leigh.anderson@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?ID=1712&S=E>

From: Muradyan, Naira
To: Anderson, Leigh
Subject: RE: K212224/S001 ((SESE)) Ready for (b)(5)
Date: Monday, September 20, 2021 9:52:10 AM
Attachments: (b)(5)

(b)(5)

Thanks
Naira

From: Anderson, Leigh <Leigh.Anderson@fda.hhs.gov>
Sent: Friday, September 10, 2021 9:56 AM
To: Muradyan, Naira <Naira.Muradyan@fda.hhs.gov>
Subject: RE: K212224/S001 ((SESE)) (b)(5)

(b)(5)

Thanks!
Leigh

From: Muradyan, Naira <Naira.Muradyan@fda.hhs.gov>
Sent: Friday, September 10, 2021 7:19 AM
To: Anderson, Leigh <Leigh.Anderson@fda.hhs.gov>
Subject: RE: K212224/S001 ((SESE)) (b)(5)

(b)(5)

Thanks,
Naira

From: Anderson, Leigh <Leigh.Anderson@fda.hhs.gov>
Sent: Thursday, September 9, 2021 8:21 PM
To: Muradyan, Naira <Naira.Muradyan@fda.hhs.gov>
Subject: K212224/S001 ((SESE)) (b)(5)

Dear Naira,

(b)(5)

Please let me know if you have any questions.

Thanks,
Leigh

Leigh Anderson

Biomedical Engineer

Neurointerventional Devices Team

DHT5A: Division of Neurosurgical, Neurointerventional and Neurodiagnostic Devices

OHT5: Office of Neurological and Physical Medicine Devices

Office of Product Evaluation and Quality

CDRH | Food and Drug Administration

White Oak, Bldg. 66, Rm. 4276 | 10903 New Hampshire Avenue | Silver Spring, MD 20993

Ph: 301-796-5613

leigh.anderson@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?ID=1712&S=E>

Dear Ms. Ellis,

Thank you for your email reply and confirmation with the (b)(4)

Regards,

Leigh Anderson

Biomedical Engineer

Neurointerventional Devices Team

DHT5A: Division of Neurosurgical, Neurointerventional and Neurodiagnostic Devices

OHT5: Office of Neurological and Physical Medicine Devices

Office of Product Evaluation and Quality

CDRH | Food and Drug Administration

White Oak, Bldg. 66, Rm. 4276 | 10903 New Hampshire Avenue | Silver Spring, MD 20993

Ph: 301-796-5613

leigh.anderson@fda.hhs.gov<mailto:leigh.anderson@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?ID=1712&S=E>

THIS MESSAGE IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review, disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify the sender by e-mail or phone.

From: Kristin Ellis <kellis@imperativecare.com>

Sent: Monday, September 20, 2021 11:20 AM

To: Anderson, Leigh <Leigh.Anderson@fda.hhs.gov>

Cc: K212224@docs.fda.gov; Nora Hadding <nhadding@imperativecare.com>

Subject: [EXTERNAL] RE: K212224 (b)(4)

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Good morning Ms. Anderson,

(b)(4)

Kind regards,

Kristin Ellis

Regulatory Affairs Manager

[cid:image001.png@01D7AE11.B637DB70]

M: +1.408.857.0934

E: kellis@imperativecare.com<<mailto:kellis@imperativecare.com>>

[imperativecare.com](http://www.imperativecare.com/)<<http://www.imperativecare.com/>> |
[LinkedIn](https://www.linkedin.com/company/imperativecare/)<<https://www.linkedin.com/company/imperativecare/>> |
[Twitter](https://twitter.com/imperative_care)<https://twitter.com/imperative_care> |
[YouTube](https://www.youtube.com/channel/UCOXtDHTSq28ZgSHkgtwPhyA)<<https://www.youtube.com/channel/UCOXtDHTSq28ZgSHkgtwPhyA>>

1359 Dell Avenue, Campbell, CA 95008

www.imperativecare.com<<http://www.imperativecare.com/>>

From: Anderson, Leigh <Leigh.Anderson@fda.hhs.gov<<mailto:Leigh.Anderson@fda.hhs.gov>>>

Sent: Monday, September 20, 2021 7:05 AM

To: Kristin Ellis <kellis@imperativecare.com<<mailto:kellis@imperativecare.com>>>

Cc: K212224@docs.fda.gov<<mailto:K212224@docs.fda.gov>>

Subject: K212224

(b)(4)

Dear Ms. Ellis,

(b)(4)

Regards,

Leigh Anderson

Biomedical Engineer

Neurointerventional Devices Team

DHT5A: Division of Neurosurgical, Neurointerventional and Neurodiagnostic Devices

OHT5: Office of Neurological and Physical Medicine Devices

Office of Product Evaluation and Quality

CDRH | Food and Drug Administration

White Oak, Bldg. 66, Rm. 4276 | 10903 New Hampshire Avenue | Silver Spring, MD 20993

Ph: 301-796-5613

leigh.anderson@fda.hhs.gov<<mailto:leigh.anderson@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?ID=1712&S=E&https://nam12.safelinks.protocol.outlook.com/?url=https%3A%2F%2Fwww.research.net%2Fs%2Fcdrhcustomerservice%3FID%3D1712%26S%3DE&data=04%7C01%7Ckellis%40imperativecare.com%7Cd7b9db26fc7a46b3d97d08d97c3fccd3%7Cf9bc67a2b9bd4bcc974aec60ef533fdc%7C0%7C0%7C637677436365610163%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6IklhaWwiLCJXVCI6Mn0%3D%7C1000&sdata=SaLEvTiPiAajPQHAfmoHGnUw4jF7Invq5s6AwSp878HA%3D&reserved=0>

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

THIS MESSAGE IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review, disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify the sender by e-mail or phone.

Dear Ms. Anderson,

Thank you for the correction of the review clock day. Can you please provide me with the submission timing review goal for this Special 510(k)? This would be helpful for our planning purposes.

Kind regards,

Kristin Ellis

Regulatory Affairs Manager

[cid:image001.png@01D7A94D.3CCDDFA0]

M: +1.408.857.0934

E: kellis@imperativecare.com<<mailto:kellis@imperativecare.com>>

[imperativecare.com](http://www.imperativecare.com/)<<http://www.imperativecare.com/>> |
[LinkedIn](https://www.linkedin.com/company/imperativecare/)<<https://www.linkedin.com/company/imperativecare/>> |
[Twitter](https://twitter.com/imperative_care)<https://twitter.com/imperative_care> |
[YouTube](https://www.youtube.com/channel/UCOXtDHTSq28ZgSHkgtwPhyA)<<https://www.youtube.com/channel/UCOXtDHTSq28ZgSHkgtwPhyA>>

1359 Dell Avenue, Campbell, CA 95008

www.imperativecare.com<<http://www.imperativecare.com/>>

From: Anderson, Leigh <Leigh.Anderson@fda.hhs.gov>

Sent: Tuesday, September 14, 2021 9:22 AM

To: Kristin Ellis <kellis@imperativecare.com>

Cc: Nora Hadding <nhadding@imperativecare.com>; K212224@docs.fda.gov

Subject: RE: [EXTERNAL] K212224 Review Status

Dear Ms. Ellis,

Thank you for your email.

Our review tracking system indicates that today is day 31 of FDA's review clock for K212224. The submission is still under review at this time. If we have additional questions, we will reach out as soon as possible.

Regards,

Leigh Anderson

Biomedical Engineer

Neurointerventional Devices Team

DHT5A: Division of Neurosurgical, Neurointerventional and Neurodiagnostic Devices

OHT5: Office of Neurological and Physical Medicine Devices

Office of Product Evaluation and Quality

CDRH | Food and Drug Administration

White Oak, Bldg. 66, Rm. 4276 | 10903 New Hampshire Avenue | Silver Spring, MD 20993

Ph: 301-796-5613

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?ID=1712&S=E<https://nam12.safelinks.prot>
[ection.outlook.com/?url=https%3A%2F%2Fwww.research.net%2Fs%2Fcdrhcustomerservice%3FID%3](https://www.research.net/s/cdrhcustomerservice?ID=1712&S=E<https://nam12.safelinks.prot)
[D1712%26S3DE&data=04%7C01%7Ckellis04imperativecare.com%7C41d7389c973f4ad8b56608d9779b](https://www.research.net/s/cdrhcustomerservice?ID=1712&S=E<https://nam12.safelinks.prot)
[b9f6%7C9fbc67a2b9bd4bcc974aec06ef533fdc%7C0%7C0%7C637672333015015148%7CUnknown%7CTWFpbG](https://www.research.net/s/cdrhcustomerservice?ID=1712&S=E<https://nam12.safelinks.prot)
[Zsb3d8eyJWlUj01MC4wLjAwMDA1LCJQJoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C1000&sdata=c](https://www.research.net/s/cdrhcustomerservice?ID=1712&S=E<https://nam12.safelinks.prot)
[DJ96Wm7afcUx0V%2FEKUsK0zIJoLhzHHSdUcEm0CE2iw%3D&reserved=0>](https://www.research.net/s/cdrhcustomerservice?ID=1712&S=E<https://nam12.safelinks.prot)

THIS MESSAGE IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review, disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify the sender by e-mail or phone.

From: Kristin Ellis <kellis@imperativecare.com<mailto:kellis@imperativecare.com>>
Sent: Tuesday, September 14, 2021 11:48 AM
To: Anderson, Leigh <Leigh.Anderson@fda.hhs.gov<mailto:Leigh.Anderson@fda.hhs.gov>>
Cc: Nora Hadding <nhadding@imperativecare.com<mailto:nhadding@imperativecare.com>>
Subject: [EXTERNAL] K212224 Review Status

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Good morning Ms. Anderson,

I hope this email finds you well. I am contacting you with regards to the review status of K212224. With the request for additional information hold and the Labor Day holiday, I am unsure of the review clock day count. I believe the clock is currently at Day 32. Can you please confirm if this is correct or if not, what date is the end of the review cycle?

Additionally, please let me know if there is any further information you require to complete the review.

Kind regards,

Kristin Ellis

Regulatory Affairs Manager

[cid:image001.png@01D7A94D.3CCDDFA0]

M: +1.408.857.0934

E: kellis@imperativecare.com<<mailto:kellis@imperativecare.com>>

imperativecare.com<http://www.imperativecare.com/> |
 LinkedIn<https://nam12.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.linkedin.com%2Fcompany%2Fimperativecare%2F&data=04%7C01%7Ckellis%40imperativecare.com%7C41d7389c973f4ad8b56608d2f779bb9f6%7Cf9bcb67a2b9bd4bcc974aec60ef533fdc%7C0%7C0%7C63767233015015148%7CUnknown%7CTWFeppbGZsb3d8eyJWIjoIMC4wLjAwMDA%7CJCQIjoiV2luMzIiLCJBTEI6IklhaWwiLCJXVCi6

Mn0%3D%7C1000&sdata=Y9Tbi5VmjZ23RCWbX1lqAjXWiaGY5qBvwqqDjOD9hpw%3D&reserved=0> |
Twitter<https://nam12.safelinks.protection.outlook.com/?url=https%3A%2F%2Ftwitter.com%2Fimperative_care&data=04%7C01%7Ckellis%40imperativecare.com%7C41d7389c973f4ad8b56608d9779bb9f6%7Cf9bc67a2b9bd4bcc974aec60ef533fdc%7C0%7C0%7C637672333015015148%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6IklhaWwiLCJXVCI6Mn0%3D%7C1000&sdata=17iP23PU%2F9LwaYyBHw4gml5fvYnRetNO%2Bw45kI1zi0Y%3D&reserved=0> |
YouTube<https://www.youtube.com/channel/UCOXtDHTSq28ZgSHkgtwPhyA>

1359 Dell Avenue, Campbell, CA 95008

www.imperativecare.com<http://www.imperativecare.com/>

Contains Nonbinding Recommendations

Appendix C. Acceptance Checklist for Special 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 application.

510(k)#:

Date Received by DCC:

510(k) Lead Reviewer:

Center:

Office:

Division:

Decision: Accept _____ Refuse to Accept _____

If Accept, notify the submitter.

If Refuse to Accept, notify submitter electronically and include a copy of this checklist.

Is an Addendum attached?: Yes No

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.

Special 510(k) Factors		
(See "The Special 510(k) Program," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/special-510k-program)		
Please complete the below questions to determine if the 510(k) is appropriate for review as a Special 510(k). Complete the Refuse to Accept Checklist for a Traditional 510(k) if submission is converted.		
		Yes No
1.	510(k) is submitted to modify a legally marketed device (predicate) AND the Special 510(k) submission is submitted by the manufacturer legally authorized to market the predicate device.	X ☐
	Comments: The predicates are the legally marketed LDP Catheters manufactured by Imperative Care.	
2.	Performance data are needed to evaluate the change. <i>If a manufacturer determines under their design control procedures that no additional verification or validation testing is necessary to evaluate a change, manufacturers may submit these changes as a Special 510(k) with a clear rationale supporting their conclusion that no performance data are necessary. When FDA does not agree with the manufacturer's assessment, FDA intends to</i>	X ☐

Contains Nonbinding Recommendations

	<i>continue with the additional Special 510(k) factors.</i>		
	Comments: Performance data are needed to evaluate the change and provided in Section 21 of the Special 510(k).		
3.	There is a well-established method to evaluate the change. <i>Well-established methods include those used in the previously cleared 510(k), an FDA-recognized consensus standard or FDA guidance document, qualified medical device development tools (MDDTs), are widely available and accepted, or found acceptable through a different premarket submission by the same manufacturer of the predicate.</i>	X	☐
	Comments: Well-established methods previously submitted to the FDA were used to evaluate the changes. Location of the methods in the prior submissions is provided in the Special 510(k).		
4.	The data be reviewed in a summary or risk analysis format. <i>The results from verification and validation associated with design or labeling changes should be able to be placed in a summary or risk analysis format without losing information necessary to support SE. Complete test reports should not be submitted in a Special 510(k). If complete test reports are submitted, FDA intends to assess whether the information can be reviewed in a summary format before converting to a Traditional 510(k).</i>	X	☐
	Comments: The data is provided in summary format in the Special 510(k).		

Is the submission appropriate for review as a Special 510(k)? *Answer Yes if the change was submitted by the manufacturer of the predicate, well-established methods are available for any performance data necessary, and performance data can be reviewed in a summary or risk analysis format.*

X Yes, submission is appropriate for a Special 510(k). Continue checklist below.

☐ No, submission is not appropriate for a Special 510(k). Discontinue this RTA checklist, convert to a Traditional and apply the Traditional checklist.

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.	X	☐	pp. 2-3
2.	Each section is labeled (e.g., headings or tabs designating Device Description section, Labeling section, etc.).	X	☐	throughout

Contains Nonbinding Recommendations

3.	All pages of the submission are numbered. <i>All pages should be numbered in such a manner that information can be referenced by page number. This may be done either by consecutively numbering the entire submission, or numbering the pages within a section (e.g., 12-1, 12-2...).</i>	X	☐	See comment
4.	Type of 510(k) is identified (i.e., Traditional, Abbreviated, or Special) <i>If type of 510(k) is not designated, review as a Traditional 510(k).</i>	X	☐	p. 1
Comments: The pages in the main body of this Special 510(k) submission are consecutively numbered. Each Appendix is individually paginated.				

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 the 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.

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 located. Use the comments section for an element if additional space is needed to identify the location of supporting information.		Yes	No	N/A	*Page #
A.	Administrative				
1.	All content used to support the submission is written in English (including translations of test reports, literature articles, etc.).	X	☐		throughout
	Comments: All content is written in English.				
2.	Submission identifies the following (FDA recommends use of the CDRH Premarket Review Submission Cover Sheet form (Form 3514 , available at https://www.fda.gov/media/72421/download)):				
a.	Device trade/proprietary name	X	☐		Section ii, p. 2

Contains Nonbinding Recommendations

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 located. Use the comments section for an element if additional space is needed to identify the location of supporting information.		Yes	No	N/A	*Page #
	b. Device class and panel OR Classification regulation OR Statement that device has not been classified with rationale for that conclusion	X	☐		Section iii, p. 3
	Comments: Trade Name: TracStar LDP and Zoom 88 LDP, Class II, Neurology Panel, 21 CFR 870.1250, Product Codes DQY and QJP				
3.	Submission contains an Indications for Use Statement with Rx	X	☐		Appendix 5-1, p. 1
	and/or OTC designated (see also 21 CFR 801.109, and FDA's guidance "Alternative to Certain Prescription Devices Labeling Requirements," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/alternative-certain-prescription-device-labeling-requirements .) <i>See recommended format</i> <i>(https://www.fda.gov/media/86323/download).</i>				
	Comments: Submission contains completed FORM FDA 3881 in Appendix 5-1.				
4.	Submission contains a 510(k) Summary or 510(k) Statement. <i>Refer to 21 CFR 807.92 and 21 CFR 807.93 for contents of 510(k) Summary and Statement, respectively. Adequacy of the content will be assessed during substantive review.</i>	X	☐		Appendix 6-1, pp. 1-6
	Comments: A 510(k) Summary is provided in Appendix 6-1.				
5.	Submission contains a Truthful and Accuracy Statement per 21 CFR 807.87(I). <i>See recommended format (https://www.fda.gov/medical-devices/premarket-notification-510k/premarket-notification-truthful-and-accurate-statement).</i>	X	☐		Appendix 7-1, p.1
	Comments: A Truthful and Accurate Statement is provided in Appendix 7-1.				
6.	Submission is a Class III 510(k) Device. <i>Select "N/A" only if submission is not a Class III 510(k).</i>	☐		X	Section 8, p. 6

Contains Nonbinding Recommendations

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 located. Use the comments section for an element if additional space is needed to identify the location of supporting information.		Yes	No	N/A	*Page #
	a. Contains Class III Summary and Certification per 21 CFR 807.87(k). <i>See recommended content (https://www.fda.gov/medical-devices/premarket-notification-510k/premarket-notification-class-iii-certification-and-summary). Select "N/A" only if submission is not a Class III 510(k).</i>	☐	☐	X	N/A
	Comments: The submission is for a Class II device.				
7.	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), Q-Submission, IDE, PMA, etc.). OR	X	☐		Section ii, p. 3 Section 4, p. 5
	States that there were no prior submissions for the subject device. <i>Prior submissions (or no prior submissions) for this device should be included in Section F (prior related submissions) of the CDRH Premarket Review Submission Cover Sheet form (Form 3514, available at https://www.fda.gov/media/72421/download). This information may also be included in the Cover Letter (i.e., as a statement that there were no prior submissions for the device or a listing of the number(s) of the prior submissions).</i>	☐	☐		
	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. <i>To address this criterion, it is recommended that the submission include a separate section with the prior submission number(s), a copy of the FDA feedback (e.g., letter, meeting minutes), and a statement of how or where in the submission this prior feedback was addressed. Note that adequacy of how the feedback was addressed will be assessed during the substantive review.</i> <i>Select "N/A" if the submitter states there were no prior submissions.</i>	☐	☐	X	N/A
	Comments: There are no outstanding issues related to a determination of substantial equivalence from prior submissions for this device. Prior submissions are identified in the CDRH Cover Sheet and Section 4 of the Special 510(k).				

Contains Nonbinding Recommendations

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 located. Use the comments section for an element if additional space is needed to identify the location of supporting information.				Yes	No	N/A	*Page #
	8.	The submission utilizes voluntary consensus standard(s) (See section 514(c) of the FD&C Act). <i>This includes both FDA-recognized and non-recognized consensus standards. Select "N/A" if the submission does not utilize voluntary consensus standards.</i>		X		☐	Section 10, pp 6-11
		a.	The submission cites FDA-recognized voluntary consensus standard(s).	X		☐	Section 10, pp 7-11
		i.	The submission includes a Declaration of Conformity (DOC) as outlined in FDA's guidance "<u>Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices</u>," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/appropriate-use-voluntary-consensus-standards-premarket-submissions-medical-devices. OR If citing general use of a standard as noted in FDA's guidance "<u>Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices</u>," the basis of such use is included along with the underlying information or data that supports how the standard was used.	X	☐		Section 10, pp 5-11
		b.	The submission cites non-FDA-recognized voluntary consensus standard(s).	X		☐	Section 10, p. 11
		i.	The basis of use is included along with the underlying information or data that supports how the standard was used.	X	☐		Section 10, p. 11
			(b)(4)				
	Combination Product Provisions – Per 503(g) of the FD&C Act. Select N/A if the product is not a combination product. 21 CFR 3.2(e). The remaining criteria in this section will be omitted from the checklist if "N/A" is selected. If you are unsure if the product is a combination product, consult with the CDRH Product Jurisdiction Officer or CBER Product Jurisdiction Officer.					X	N/A

Contains Nonbinding Recommendations

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 located. Use the comments section for an element if additional space is needed to identify the location of supporting information.		Yes	No	N/A	*Page #
9.	Submission identifies the product as a combination product.	☐	X		N/A
10.	The combination product contains as a constituent part an approved drug as defined in section 503(g)(5)(B) of the FD&C Act. Select "N/A" if the combination product does not contain as a constituent part an approved drug. Please also select "N/A" if a right of reference or use for the drug constituent part(s) is included with the submission. If "N/A" is selected, part a below is omitted from the checklist.	☐		X	N/A
a.	The submission includes appropriate patent statement or certification and a statement that the submitter will give notice, as applicable. See 503(g)(5)(A)&(C).	☐	X		N/A
Comments: The device is not a combination product.					
B. Device Description					
11.	The device has a device-specific guidance document, special controls, and/or requirements in a device-specific classification regulation regarding the device description that is applicable to the subject device. <i>If "N/A" is selected, parts a and b below are omitted from the checklist.</i>	☐		X	N/A
a.	The submission addresses device description recommendations outlined in the device-specific guidance. OR The submission provides an alternative approach intended to address the applicable statutory and/or regulatory criteria. <i>Select "N/A" if there is no applicable device-specific guidance. Select "No" if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how recommendations in a device-specific guidance, etc., have been addressed should be assessed during the substantive review.</i>	☐	☐	X	N/A

Contains Nonbinding Recommendations

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 located. Use the comments section for an element if additional space is needed to identify the location of supporting information.				Yes	No	N/A	*Page #
		b.	The submission includes device description information that addresses relevant mitigation measures set forth in the special controls or device-specific classification regulation applicable to the device. <u>OR</u> The submission uses alternative mitigation measures and provides rationale why the alternative measures provide an equivalent assurance of safety and effectiveness. <i>Select "N/A" if there are no applicable special controls or device-specific classification regulation. Select "No" if the submission does not include a rationale for any omitted information or any alternative approach as outlined above.</i>	☐	☐	X	N/A
			<i>Note that the adequacy of how such mitigation measures have been addressed should be assessed during the substantive review.</i>				
		Comments: The TracStar LDP and Zoom 88 LDP are classified under product codes DQY and QJP. There are no device specific guidance documents, special controls or regulations associated with these product codes.					
	12.	Descriptive information is present and consistent within the submission (e.g., the device description section is consistent with the device description in the labeling).		X	☐		Section 13.1, pp. 18-20 Appendix 16-2, p.1 Appendix 16-4, p.1
		Comments: The descriptive information is present and is consistent with the proposed labeling.					
	13.	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.	X	☐		Section 13.5, p. 22
		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.	X	☐		Section 13.5, p. 22

Contains Nonbinding Recommendations

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 located. Use the comments section for an element if additional space is needed to identify the location of supporting information.				Yes	No	N/A	*Page #
	c.	A list and description of each device for which clearance is requested. <i>Select "N/A" if there is only one device or model. "Device" may refer to models, part numbers, various sizes, etc.</i>		X	☐	☐	Section 13.9, p. 28
	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). <i>In lieu of engineering drawings, schematics, etc. of each device to be marketed, "representative" drawings, etc. may be provided, where "representative" is intended to mean that the drawings, etc. provided capture the differences in design, size, and other important characteristics of the various models, sizes, or versions of the device(s) to be marketed.</i>		X	☐		Appendix 13-2, pp. 1-5 Appendix 13-3, pp. 1-5
	Comments: Submission contains descriptive information of the device.						
	14.	A detailed description of all device modification(s) including rationale for each modification. <i>When labeling or specific technological characteristics (e.g., materials, dimensions) are unchanged in comparison to the predicate, the submission should clearly state that no changes were made.</i>		X	☐		Section 14, pp. 29-38
	Comments: Submission contains description of device modifications including a rationale for each modification.						
	15.	Device is intended to be marketed with accessories and/or as part of a system. <i>Select "N/A" if the device is not intended to be marketed with accessories and/or as part of a system. If "N/A" is selected, parts a-c below are omitted from the checklist.</i>		X		☐	Section 13.2, p. 20
	a.	Submission includes a list of all accessories to be marketed with the subject device.		X	☐		Section 13.2, p. 20

Contains Nonbinding Recommendations

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 located. Use the comments section for an element if additional space is needed to identify the location of supporting information.				Yes	No	N/A	*Page #
	b.	Submission includes a description (as detailed in item 13a., 13b., and 13d. above) of each accessory. <i>Select "N/A" if the accessory(ies) has been previously cleared, or is exempt, and the proposed indications for use are consistent with the cleared indications.</i>		X	☐	☐	Section 13.2, p. 20
	c.	A 510(k) number is provided for each accessory that received a prior 510(k) clearance AND A statement is provided that identifies accessories that have not received prior 510(k) clearance.		X	☐		Section 13.2, p. 20
(b)(4)							
C. Substantial Equivalence Discussion							
16.	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, classification regulation reference, if exempt (e.g., 21 CFR 872.3710), or statement that the predicate is a preamendment device). For predicates that are preamendments devices, information is		X	☐		Section 12, p. 15, Section 13.9, p. 27 Section 15, p. 39-49 Appendix 6-1, p. 1
		provided to document preamendments status. <i>Information regarding documenting preamendment status is available online (https://www.fda.gov/medical-devices/quality-and-compliance-medical-devices/preamendment-status).</i>					
	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.		X	☐		Section 12, p. 15, Section 13.9, p. 27 Section

Contains Nonbinding Recommendations

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 located. Use the comments section for an element if additional space is needed to identify the location of supporting information.				Yes	No	N/A	*Page #
							15, p. 39-49 Appendix 6-1, p. 1
		Comments: The predicate devices are the TracStar LDP, Zoom 88 LDP, and Zoom 88-T LDP, K203764.					
	17.	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)] <i>See the FDA guidance document "<u>The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]</u>," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/510k-program-evaluating-substantial-equivalence-premarket-notifications-510k for more information on comparing intended use and technological characteristics.</i>					
		a.	Indications for use <i>If there are no differences between the subject device and the predicate(s) with respect to indications and intended use, this should be explicitly stated.</i>	X	☐		Section 15.1, p. 39
		b.	Technology, including technical specifications, features, materials, and principles of operation <i>Examples of technological characteristics include, but are not limited to design, features, materials, energy source, and principle of operation.</i> <i>FDA recommends a tabular format for comparing</i>	X	☐		Section 15.2, pp. 39-49
			<i>technological characteristics. Any characteristic that is the same as the predicate(s) should be explicitly stated. Differences in technological characteristics should be identified and a rationale provided why they do not raise different questions of safety and effectiveness.</i>				

Contains Nonbinding Recommendations

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 located. Use the comments section for an element if additional space is needed to identify the location of supporting information.				Yes	No	N/A	*Page #
D. Design Control Activities							
18.	Design Control Activities Summary includes all of the following:						
	a.	Identification of risk analysis method(s) used to assess the impact of the modification on the device AND the results of the analysis.		X	☐		Section 11.2, pp. 13-14 Section 14.0, pp. 32-38
	b.	Identification of the device change(s).		X	☐		Section 14.0, pp. 28-38
	c.	Identification of all risks associated with each device change, including identification of risks that are considered new because of the change; and		X	☐		Section 14.0, pp. 32-38
	d.	Risk control measures to mitigate identified risks (e.g., labeling, verification).		X	☐		Section 14.0, pp. 32-38
	e.	Based on the Risk Analysis, an identification of the verification and/or validation activities required to comply with 21 CFR 820.30. This identification includes a summary of test methods (including any protocol deviations), acceptance criteria, results in a summary or risk analysis format (e.g., basic descriptive statistics, where appropriate), and why each is adequate to establish substantial equivalence. If unchanged from a previous premarket submission, the manufacturer references the location of protocols and acceptance criteria by providing a submission and section numbers.		X	☐		Section 14.0, pp. 32-38
	i.	For non-standardized test methods only: A reference to the protocol used for the existing device with an identification of any differences (e.g., protocol, test conditions, pre-defined acceptance criteria, sample size) from the previous 510(k). If protocol changes were made, the results summary describes why the test methods, acceptance criteria, and results support SE.		X	☐	☐	Section 14.0, pp. 32-38

Contains Nonbinding Recommendations

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 located. Use the comments section for an element if additional space is needed to identify the location of supporting information.				Yes	No	N/A	*Page #
		f.	A signed statement by the manufacturer's designated individual(s) responsible for design control activities. Both items below must be present to answer "Yes." i. Statement that, as required by the risk analysis, all verification and validation activities were performed by designated individual(s) and the results demonstrated that the predetermined acceptance criteria were met. ii. Statement that the submitter has complied and is not currently in violation of the design control procedure requirements as specified in 21 CFR 820.30 and the records are available for review, upon request.	X	☐		Appendix 11-1. p. 1
Comments: Submission contains Summary of Design Control, Risk Management, and Declaration of Conformity							
E.	Proposed Labeling (see also 21 CFR parts 801 and 809 as applicable)						
	19.	Submission includes proposed package labels and labeling (e.g., instructions for use, package insert, operator's manual).		X	☐		Appendix 16-2, 16-4, 16-5, 16-6, 16-7, 16-8, 16-9, 16-10
		a.	All changes in proposed labeling resulting from device modification(s) are highlighted or prominently identified. <i>FDA recommends clean and redlined copies be provided.</i>	X	☐		Appendix 16-1, 16-3, 16-11
Comments: Submission includes clean copies of the IFUs and product labels. Submission includes redline copies of IFUs and representative product label.							

Digital Signature Concurrence Table	
Reviewer Sign-Off	
Management Sign-Off (digital signature optional)*	

*Management review of checklist and concurrence with decision required.

**PREMARKET NOTIFICATION
DESIGN CONTROL DECLARATION OF CONFORMITY**

I certify in my capacity as Manager, Research and Development at Imperative Care Inc. that to the best of my knowledge Imperative Care Inc. is in conformance with the design control requirements as specified in 21 CFR 820.30 and that all required records are available for review.

I further certify that the verification and validation activities required per the risk assessments for all changes were performed by designated individuals and the results demonstrated that the predetermined acceptance criteria were met.

(b)(6)

Josh Wu, Manager, Research and Development

JULY 15, 2021

Date

Imperative Care Inc.
1359 Dell Avenue
Campbell, CA 95008