

Thank you for your response, Kirsten. I was hoping you could please address the following as well:

(b)(4)

If you could please respond by noon Eastern on Wednesday (09/28), then it will help facilitate our review. If possible, please kindly confirm acceptance of this email at your earliest convenience.

Thank you again.

-Nick

From: Kirsten Valley <kirsten@r92m.com>
Sent: Sunday, September 25, 2022 10:55 AM
To: Clay, Nicholas <Nicholas.Clay@fda.hhs.gov>
Cc: K222743@docs.fda.gov
Subject: [EXTERNAL] Re: Additional Questions Regarding K222743

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.

Hello Nick,

Attached, please find the responses to your questions. Please let me know if you have any additional questions.

Many thanks,

Kirsten

Route 92 Medical
650-279-8427

From: "Clay, Nicholas" <Nicholas.Clay@fda.hhs.gov<mailto:Nicholas.Clay@fda.hhs.gov>>
Date: Thursday, September 22, 2022 at 9:19 PM
To: Kirsten Valley <kirsten@r92m.com<mailto:kirsten@r92m.com>>
Cc: "K222743@docs.fda.gov<mailto:K222743@docs.fda.gov>"
<K222743@docs.fda.gov<mailto:K222743@docs.fda.gov>>
Subject: Additional Questions Regarding K222743

Good afternoon Kirsten:

As we continue our review of K222743, I was wondering if you could please answer the following questions:

(b)(4)

If you could please respond to this request by 9 am (Eastern) on 09/26, then it will help facilitate our review.

Please let me know if you want to discuss further. Thank you again.

Nicholas E. Clay, Ph.D.

Acting Team Lead

THT5A2: Neurointerventional Devices

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

10903 New Hampshire Avenue

Silver Spring, MD 20993

nicholas.clay@fda.hhs.gov<<mailto:nicholas.clay@fda.hhs.gov>>

[cid:image001.png@01D8D1DE.6D6A2F50]<<http://www.fda.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=1510&S=E<https://secure-web.cisco.com/lpafvORR1D20HswXAk5ZXSD6-7OcBYIpEFUcYXmH2BSn4h-k7De0RYKHmLz6i_11FiilU9a4LIan-83edBKZYeOiBGa-_GJ2083e7-zAlfjJK-VJgo6AziVbJ5mrhs8AGnvEB_o0RmHKMbHsClWdvgcF90Bb3naiiTT6KpWlzkGj20xUwbXBpkaFrjrqrAzOrFWjY-dQFGarIRuOX5QJvcH4NVNAkkDx_24e5YqIhbU/https%3A%2F%2Fwww.research.net%2Fs%2Fcdrhcustomer-service%3FID%3D1510%26S%3DE>

Responses to Interactive September 22, 2022 Email Request for K222743

(b)(4)

(b)(4)

Good afternoon Kirsten:

As we continue our review of K222743, I was wondering if you could please answer the following questions:

(b)(4)

If you could please respond to this request by **9 am (Eastern) on 09/26**, then it will help facilitate our review.

Please let me know if you want to discuss further. Thank you again.

Nicholas E. Clay, Ph.D.

Acting Team Lead

THSA2: Neurointerventional Devices
DHTSA: Division of Neurosurgical, Neurointerventional and Neurodiagnostic Devices
OHTS: Office of Neurological and Physical Medicine Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health
16903 New Hampshire Avenue
Silver Spring, MD 20993

nicholas.clay@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=1510&S=E>

510(k) Summary

(b)(4)

(b)(4)

(b)(4)

(b)(4)

TABLE OF CONTENTS

i. **Medical Device User Fee Cover Sheet (Form FDA 3601)**.....i-1
ii. **CDRH Premarket Review Submission Cover Sheet (FDA Form 3514)**.....ii-1
iii. **Acceptance Checklist for Special 510(k)s**.....iii-1
iv. **Cover Letter**..... iv-1

1. Indications For Use Statement2
2. 510(k) Summary3
3. Truthful and Accuracy Statement4
4. Device Description and Comparison to Predicate Device5
 4.1. **Indications for Use**5
 4.2. **Principles of Operation**.....5
 4.3. **Device Description**5
 4.4. **Comparison to Predicate Device**.....9
5. Design Control Activities17
 5.1. **Risk Analysis**17
 5.2. **Verification and Validation Activities**.....17
6. Proposed Labeling.....27
7. Substantial Equivalence Discussion.....28

List of Appendices

Appendix A: Indications for Use Statement, FORM FDA 3881

Appendix B: 510(k) Summary

Appendix C: Declaration of Conformity with Design Controls

Appendix D: Direction for Use, Modified Device (clean and redlined)

Appendix E: Proposed Labels for Modified Device

1. INDICATIONS FOR USE STATEMENT

Please refer to **Appendix A** for the Indications for Use Statement, FORM FDA 3881.

2. 510(K) SUMMARY

Please refer to **Appendix B** for the 510(k) Summary.

3. TRUTHFUL AND ACCURACY STATEMENT

[As required by 21 CFR 807.87(k)]

I certify that, in my capacity as Chief Operating Officer at Route 92 Medical, that to the best of my knowledge all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.

(b)(6)

Kirsten Valley
Chief Operating Officer
Route 92 Medical, Inc.

September 8, 2022

Date

4. DEVICE DESCRIPTION AND COMPARISON TO PREDICATE DEVICE

The subject of this application is a modification to the legally marketed Predicate Device, Route 92 Medical Full Length 088 Access System cleared under K210635. The Modified Device, the Route 92 Medical Full Length 070 Access System, is a modification of the Route 92 Medical Full Length 088 Access System. (b)(4)

(b)(4)
(b)(4). There are no differences in the indications for use as shown in Section 4.1 below. Both the Full Length 088 Access System and the Full Length 070 Access System include a Full Length Support Catheter and a Delivery Catheter. The subject Full Length 070 Support Catheter has an inner diameter of 0.070” as compared to the predicate Full Length 088 Support Catheter which has an inner diameter of 0.088.” This well-defined modification to the legally marketed device was subjected to rigorous design control requirements, risk analysis and verification and validation testing using well-established test methods to evaluate the modification.

4.1. Indications for Use

The indications for use for the Full Length 070 Access System (modified device) are as stated below:

The Route 92 Medical Full Length 070 Access System is indicated for use with compatible catheters in facilitating the insertion and guidance of microcatheters into a selected blood vessel in the neurovascular system.

There are no differences between the subject/modified device and the predicate device with respect to indications and intended use.

4.2. Principles of Operation

The principles of operation are unchanged from the predicate device. The Support Catheter is placed through a guide catheter. The provided Delivery Catheter facilitates navigation of the Support Catheter through the vasculature. After removal of the Delivery Catheter, the Support Catheter provides a lumen for the introduction of microcatheters.

4.3. Device Description

Predicate Device

The Route 92 Medical Full Length 088 Access System (K210635), or Predicate Device, is comprised of the Full Length 088 Support Catheter and the 088 Delivery Catheter and does not include any accessories and is not intended to be marketed as part of a system.

The Full Length 088 Support Catheter (Predicate Device) is a single-lumen, coil-reinforced, variable stiffness polymer shaft catheter (**Figure 4-1**). The distal 65cm of the polymer shaft is

coated with a hydrophilic coating.

(b)(4)

(b)(4)

Figure 4-1: Predicate Route 92 Medical Full Length 088 Support Catheter

The 088 Delivery Catheter (Predicate Device) is a single-lumen, variable stiffness catheter with a long, smooth, tapered tip delineated by two radiopaque markers as illustrated in **Figure 4-2**. The distal 90 cm of the catheter shaft is hydrophilically coated.

(b)(4)

(b)(4)

Figure 4-2: Predicate Device Route 92 Medical 088 Delivery Catheter

The Support Catheter and Delivery Catheter are used together as a system as shown in **Figure 4-3**. The Delivery Catheter is inserted into the Support Catheter via an RHV (rotating hemostasis valve) and facilitates placement of the Support Catheter at the targeted site. Both the Delivery Catheter and the Support Catheter are coated with a hydrophilic coating to minimize friction and facilitate movement.

(b)(4)

Figure 4-3: Predicate Device Route 92 Medical Full Length 088 Access System, with Delivery Catheter Inserted into Support Catheter

To place the Access System, a standard neurovascular guidewire may be used through the Delivery Catheter. The Delivery Catheter is inserted through the Support Catheter and the Delivery Catheter/Support Catheter assembly is inserted as a system through a guide sheath placed in the femoral artery. The system is advanced to the targeted location under fluoroscopy using standard endovascular techniques. Once the Support Catheter is positioned at the target site, the Delivery Catheter is removed. A microcatheter may then be advanced through the Support Catheter to the targeted location in the vasculature.

Modified Device

The Route 92 Medical Full Length 070 Access System is a modification of the legally marketed Route 92 Medical Full Length 088 Access System.

The indications for use for the Full Length 070 Access System are identical to the indications for use for the Full Length 088 Access System as described in **Section 4.1**. Like the Predicate Device, the subject device includes no accessories and is not intended to be marketed as part of a system. Also like the Predicate Device, a Delivery Catheter and Support Catheter comprise the Full Length 070 Access System.

The 070 Support Catheter (Modified Device) is shown in **Figure 4-4**. Like the Predicate 088 Support Catheter, the 070 Support Catheter is a single-lumen, coil-reinforced, variable stiffness polymer shaft catheter. The distal 65cm of the polymer shaft is coated with a hydrophilic coating.

(b)(4)

(b)(4)

(b)(4)

Figure 4-4: Modified Device, Route 92 Medical 070 Support Catheter

As described above, the 070 Support Catheter (Modified Device) is identical to the Predicate 088 Support Catheter (**Figure 4-1**) except for the following modifications:

- Compared to the Predicate 088 Support Catheter, the outer diameter (0.084” vs. 0.101”) and inner diameter (0.070” vs. 0.088”) of the Modified 070 Support Catheter are smaller
- The Modified Support Catheter is provided in only one length, 132 cm; the Predicate Support Catheter is offered in two lengths, 125 cm and 132 cm

(b)(4)

The 070 Delivery Catheter (Modified Device) is shown in **Figure 4-5**. Like the predicate 088 Delivery Catheter, the 070 Delivery Catheter is a single-lumen, variable stiffness catheter with a long, smooth, tapered tip (b)(4). The distal 90 cm of the catheter shaft is hydrophilically coated. (b)(4)

(b)(4)

(b)(4)

Figure 4-5: Modified Device, Route 92 Medical 070 Delivery Catheter

As described above, the 070 Delivery Catheter is identical to the Predicate 088 Delivery Catheter (**Figure 4-2**) except for the following modifications:

- The Modified Delivery Catheter has an 0.062” outer diameter along the entire length and does not have a larger .080” distal segment

- **(b)(4)**

(b)(4)

(b)(4) serves as a Reference Device.

The principles of operation as described for the Predicate Device are unchanged. As with the Predicate Device, the Support Catheter and Delivery Catheter are used together as a system as shown below in **Figure 4-7**.

(b)(4)

Figure 4-6: Modified Device, Route 92 Medical Full Length 070 Access System, with Delivery Catheter Inserted into Support Catheter

(b)(4)

4.4. Comparison to Predicate Device

The modifications to the Predicate Device are well defined and detailed in **Table 4-1**. Specifically, the modified Route 92 Medical Full Length 070 Access System is compared to the cleared Route 92 Medical Full Length 088 Access System and the modifications are described.

Table 4-1: Comparison of the Modified Device, the Route 92 Medical Full Length 088 Access System, to the Predicate Device, the Route 92 Medical Full Length 088 Access System (K210635)			
Attribute	Route 92 Medical Full Length 088 Access System, REF 4002 (132cm), REF 4004 (125 cm), K210635 PREDICATE DEVICE	Route 92 Medical Full Length 070 Access System, REF 7002 MODIFIED DEVICE	Modification
Indications for Use	The Route 92 Medical Full Length 088 Access System is indicated for use with compatible guide catheters in facilitating the insertion and guidance of microcatheters into a selected blood vessel in the neurovascular system.	The Route 92 Medical Full Length 070 Access System is indicated for use with compatible guide catheters in facilitating the insertion and guidance of microcatheters into a selected blood vessel in the neurovascular system.	No difference.
Device Description	The Route 92 Medical Access System is comprised of a Support Catheter and a Delivery Catheter. The Support Catheter is a single-lumen, coil-reinforced variable stiffness catheter. The Delivery Catheter is a hubbed, single lumen variable stiffness catheter. Both catheters are hydrophilically coated. The devices are provided sterile and non-pyrogenic and are intended for single use only.	The Route 92 Medical Access System is comprised of a Support Catheter and a Delivery Catheter. The Support Catheter is a single-lumen, coil-reinforced variable stiffness catheter. The Delivery Catheter is a hubbed, single lumen variable stiffness catheter. Both catheters are hydrophilically coated. The devices are provided sterile and non-pyrogenic and are intended for single use only.	No difference.
User	Physicians trained in neurovascular interventional techniques	Same as Predicate Device	No difference.
Classification Regulation, Product Code	21 CFR 870.1250, Neurovascular Percutaneous Catheter, QJP	Same as Predicate Device	No difference.

Table 4-1: Comparison of the Modified Device, the Route 92 Medical Full Length 088 Access System, to the Predicate Device, the Route 92 Medical Full Length 088 Access System (K210635)			
Attribute	Route 92 Medical Full Length 088 Access System, REF 4002 (132cm), REF 4004 (125 cm), K210635 PREDICATE DEVICE	Route 92 Medical Full Length 070 Access System, REF 7002 MODIFIED DEVICE	Modification
(b)(4)			
Shelf Life	8 months	6 months	The Modified Device is labeled for 6-month shelf life; as with the Predicate Device, the labeled shelf life is supported by testing of aged devices.
Support Catheter			
Inner Diameter	0.088"	0.070"	Modified Device has a smaller inner diameter because the outer diameter has been decreased
Outer Diameter	0.101"	0.084"	Modified Device has a smaller outer diameter to accommodate different anatomies
Working Length	132 cm (REF 4002) 125 cm (REF 4004)	132 cm	The 070 Modified Device is offered in only one working length.
(b)(4)			

Table 4-1: Comparison of the Modified Device, the Route 92 Medical Full Length 088 Access System, to the Predicate Device, the Route 92 Medical Full Length 088 Access System (K210635)			
Attribute	Route 92 Medical Full Length 088 Access System, REF 4002 (132cm), REF 4004 (125 cm), K210635 PREDICATE DEVICE	Route 92 Medical Full Length 070 Access System, REF 7002 MODIFIED DEVICE	Modification
(b)(4)			
Delivery Catheter			
(b)(4)			
Inner Diameter	0.019"	Same as Predicate Device	No difference. Also, no change compared to the Reference Device (b)(4)
Outer Diameter	Distal: 0.080" Proximal: 0.062"	0.062"	Modified Device has constant outer diameter along the entire length of shaft to accommodate the smaller inner diameter lumen of the Full Length 070 Support Catheter. Also, no change compared to the Reference Device (b)(4)

Table 4-1: Comparison of the Modified Device, the Route 92 Medical Full Length 088 Access System, to the Predicate Device, the Route 92 Medical Full Length 088 Access System (K210635)

Attribute	Route 92 Medical Full Length 088 Access System, REF 4002 (132cm), REF 4004 (125 cm), K210635 PREDICATE DEVICE	Route 92 Medical Full Length 070 Access System, REF 7002 MODIFIED DEVICE	Modification
Working Length	151 cm	Same as Predicate Device	No difference. Also, no change compared to Reference Device (b)(4)

(b)(4)

As shown in **Table 4-1**, the indications for use are unchanged and the fundamental scientific technology is the same. Additionally, there are no changes to the operating principles or mechanism of action.

(b)(4)

Table 4-2: Materials Comprising the Predicate Route 92 Medical Full Length 088 Access System (K210635) and the Modified Route 92 Medical Full Length 070 Access System

(b)(4)

Table 4-2: Materials Comprising the Predicate Route 92 Medical Full Length 088 Access System (K210635) and the Modified Route 92 Medical Full Length 070 Access System

(b)(4)

(b)(4)

The Predicate Device (K210635) and the Reference Device Delivery Catheter **(b)(4)** meet all applicable biocompatibility requirements in accordance with the requirements of FDA-recognized consensus standard ISO 10993-1 for an externally communicating device, contacting circulating blood with a limited contact duration (<24 hours). The Modified Device was evaluated by a toxicologist/qualified individual for biological risk in accordance with the same requirements. The biological safety evaluation is summarized below:

- **(b)(4)**
- **(b)(4)**
- No additional biocompatibility testing is warranted. Existing biocompatibility data for the Full Length 088 Support Catheter (Predicate Device) and the Reference Device Delivery Catheter **(b)(4)** demonstrate that the Full Length 070 Support Catheter (Modified Device) meets applicable biocompatibility requirements per ISO 10993-1.

Based on this assessment, the Full Length 070 Access System (REF 7002) is biocompatible in accordance with the requirements of ISO 10993-1 for an external communicating device, contacting circulating blood with a limited contact duration (<24 hours), which supports substantial equivalence of the Modified Device to the Predicate Device.

5. DESIGN CONTROL ACTIVITIES

5.1. Risk Analysis

To assess the impact of the modifications to the cleared device, risk analysis was performed in accordance with FDA-recognized consensus standard, ISO 14971. The proposed modifications to the Predicate Route 92 Medical Full Length 088 Access System (K210635) described in **Section 4** did not result in the identification of any new risks that could occur during use, considering the safety, performance, intended use, potential misuse, biological hazards, environmental hazards, and hazards related to device failure due to design and processing. Any adverse events that may be associated with the use of the device or with the procedure were considered.

As part of the risk analysis, each modification was assessed to determine the appropriate verification and validation activities needed to demonstrate that the design outputs of the Modified Device meet the design input requirements. This analysis is shown in **Table 5-1**.

5.2. Verification and Validation Activities

Verification and validation testing was performed on the Route 92 Medical Full Length 070 Support Catheter of the Modified Device. Well-established methods were used to evaluate the device modifications compared to the Predicate Device; the same protocols used to evaluate the K210635 Predicate Device were used for assessing the Modified Device. (b)(4)

(b)(4)

(b)(4)

The confidence and reliability acceptance criteria were unchanged.

The 070 Delivery Catheter of the Modified Device is identical in all aspects, including design and intended use, to the Reference Device cleared via (b)(4). The information pertaining to performance testing of the 070 Delivery Catheter previously provided is incorporated herein by reference to (b)(4). No further testing of the 070 Delivery Catheter was required to support this current submission.

Table 5-1 summarizes the results of the risk management activities determined during the design control activities. The Modified Device met all the pre-established acceptance criteria. Like the

(b)(4)

Table 5-1: Summary of Design Control Activities

(b)(4)

Table 5-1: Summary of Design Control Activities

(b)(4)

(b)(4)

(b)(4)

(b)(4)

Table 5-1: Summary of Design Control Activities

(b)(4)

Table 5-1: Summary of Design Control Activities

(b)(4)

Table 5-1: Summary of Design Control Activities

(b)(4)

Conclusion

As required by the risk analysis, all verification and validation activities for the Modified Device, Route 92 Medical Full Length 070 Access System were performed by designated individuals, and results demonstrated that the predetermined acceptance criteria were met. In addition, Route 92 Medical is in conformance with the design control procedure requirements as specified in 21 CFR 820.30. A signed Declaration of Conformity with Design Controls containing this statement may be found in **Appendix C**.

The established methods, protocols, and acceptance criteria that were used to support the previously cleared 510(k) were applied to testing of the modified device. Rigorous design control procedures were used to evaluate the well-defined modifications. The successful completion of these verification and validation activities ensures that design outputs meet design inputs, and that the device conforms to defined user needs and intended uses. All of the pre-determined acceptance criteria were met providing evidence of safety and efficacy.

6. PROPOSED LABELING

The proposed DFU for the Modified Device, the Route 92 Medical Full Length 070 Access System, is provided in **Appendix D**, both as a clean copy and as a redline compared to the cleared DFU. The DFU for the Predicate Device was modified only to add the dimensional and compatibility information for the Full Length 070 Access System configuration. The intended use of the Modified Device, the Route 92 Medical Full Length 070 Access System, is the same as the Predicate Device, the Route 92 Medical Full Length 088 Access System (K210635).

The two proposed pouch labels (one for the Support Catheter and one for the Delivery Catheter) and the proposed shelf carton label may be found in **Appendix E**. On both the shelf carton label and the pouch labels, the drawings and dimensions have been updated to reflect the Modified Device. Of note, the Delivery Catheter will be labeled with the trade name “Tenzing 7.”

7. SUBSTANTIAL EQUIVALENCE DISCUSSION

The well-defined modifications to the Predicate Device, Route 92 Medical Full Length 088 Access System (K210635) do not impact the fundamental scientific technology of the device and there is no change to the device's operating principles or mechanism of action. In addition, the intended use and indications for use for the Modified Device, the Route 92 Medical Full Length 088 Access System, are identical to the Predicate Device.

Rigorous design control activities were employed to ensure that the Modified Device met all of the pre-established verification and validation requirements. The successful completion of these design control activities using the established acceptance criteria and testing methodology that were used to evaluate the Predicate Device demonstrates that the Full Length 070 Access System is substantially equivalent to the cleared Full Length 088 Access System (K210635).

From: [Williams, Dhanya K](#)
To: [Anderson, Leigh](#); [Muradyan, Naira](#); [Smith, Myra K.](#); [Clay, Nicholas](#)
Cc: [Williams, Dhanya K](#)
Subject: RE: [REDACTED] (b)(5) } K222743 Route 92 Medical Full Length 070 Access System
Date: Thursday, September 15, 2022 9:21:51 AM
Attachments: [image001.png](#)

Hi Leigh,

Thanks very much for your note. Nick – with Leigh’s confirmation. [REDACTED] (b)(5)

(b)(5)

Dhanya

From: Anderson, Leigh <Leigh.Anderson@fda.hhs.gov>
Sent: Wednesday, September 14, 2022 9:57 PM
To: Williams, Dhanya K <Dhanya.Kumar@fda.hhs.gov>; Muradyan, Naira <Naira.Muradyan@fda.hhs.gov>; Smith, Myra K. <Myra.Smith@fda.hhs.gov>; Clay, Nicholas <Nicholas.Clay@fda.hhs.gov>
Subject: RE: [REDACTED] (b)(5) } K222743 Route 92 Medical Full Length 070 Access System

Hi Nick and Dhanya,

(b)(5)

Thanks
Leigh

Leigh Anderson (she/her/hers)
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: Williams, Dhanya K <Dhanya.Kumar@fda.hhs.gov>

Sent: Monday, September 12, 2022 12:40 PM

To: Muradyan, Naira <Naira.Muradyan@fda.hhs.gov>; Smith, Myra K. <Myra.Smith@fda.hhs.gov>; Anderson, Leigh <Leigh.Anderson@fda.hhs.gov>; Clay, Nicholas <Nicholas.Clay@fda.hhs.gov>

Cc: Williams, Dhanya K <Dhanya.Kumar@fda.hhs.gov>

Subject: RE: (b)(5) K222743 Route 92 Medical Full Length 070 Access System

Hi Nick,

First, welcome to our team! I'm looking forward to working with you.

I took a look and here are my thoughts for the two files Naira described below:

(b)(5)

(b)(5)

Feel free to email or IM me with any other questions.

Thanks,
Dhanya

From: Muradyan, Naira <Naira.Muradyan@fda.hhs.gov>

Sent: Monday, September 12, 2022 12:13 PM

To: Williams, Dhanya K <Dhanya.Kumar@fda.hhs.gov>; Smith, Myra K. <Myra.Smith@fda.hhs.gov>;
Anderson, Leigh <Leigh.Anderson@fda.hhs.gov>; Clay, Nicholas <Nicholas.Clay@fda.hhs.gov>

Subject: (b)(5) K222743 Route 92 Medical Full
Length 070 Access System

Hi Dhanya, Leigh and Myra,

Nick will be leading the review of these two files that came in last Friday and since he's new to our devices could you please help him to get started:

(b)(5)

Thank you everyone,

Naira Muradyan, PhD
Assistant Director

Neurointerventional Devices Team

DHT5A: Division of Neurosurgical, Neurointerventional & Neurodiagnostic Devices

OHT5: Office of Neurological & Physical Medicine Devices

Office of Product Evaluation and Quality

CDRH | Food and Drug Administration

White Oak, Bldg. 66 Rm 3657 | 10903 New Hampshire Avenue | Silver Spring, MD 20993

Tel: 240-402-4918

Naira.Muradyan@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: [Smith, Myra K.](#)
To: [Clay, Nicholas](#)
Subject: RE: (b)(5) K222743 Route 92 Medical Full Length 070 Access System
Date: Thursday, September 15, 2022 2:51:05 PM
Attachments: [image001.png](#)
[image007.png](#)
[image008.png](#)
[image009.png](#)

(b)(5)

-Myra

Myra Smith, M.S.
Microbiologist

Neurointerventional Devices Team
FDA/CDRH/OHT5/DHT5A
White Oak/ Bldg 66/Rm 4206
10903 New Hampshire Ave
Silver Spring/ MD 20993
Phone: (301) 796-6507
myra.smith@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: Clay, Nicholas <Nicholas.Clay@fda.hhs.gov>
Sent: Thursday, September 15, 2022 2:47 PM
To: Smith, Myra K. <Myra.Smith@fda.hhs.gov>
Subject: RE: (b)(5) K222743 Route 92 Medical Full Length 070 Access System

Hello there Myra:

Thank you again for your email. For K222743, it is my understanding that you concur with the sponsor's rationale: (b)(5)

Thank you again.

-Nick

From: Smith, Myra K. <Myra.Smith@fda.hhs.gov>
Sent: Monday, September 12, 2022 5:12 PM
To: Clay, Nicholas <Nicholas.Clay@fda.hhs.gov>
Subject: RE: (b)(5) K222743 Route 92 Medical Full Length 070

Access System

Hi Nick,

(b)(5)

Myra Smith, M.S.
Microbiologist

Neurointerventional Devices Team
FDA/CDRH/OHT5/DHT5A
White Oak/ Bldg 66/Rm 4206
10903 New Hampshire Ave
Silver Spring/ MD 20993
Phone: (301) 796-6507
myra.smith@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: Clay, Nicholas <Nicholas.Clay@fda.hhs.gov>
Sent: Monday, September 12, 2022 1:59 PM
To: Smith, Myra K. <Myra.Smith@fda.hhs.gov>
Subject: RE: **(b)(5)** K222743 Route 92 Medical Full Length 070
Access System

Good afternoon Myra:

Thank you for your message. I look forward to working with you on these and other submissions.

(b)(5)

(b)(5)

Thank you again.

-Nick

From: Smith, Myra K. <Myra.Smith@fda.hhs.gov>

Sent: Monday, September 12, 2022 12:18 PM

To: Muradyan, Naira <Naira.Muradyan@fda.hhs.gov>; Williams, Dhanya K <Dhanya.Kumar@fda.hhs.gov>;
Anderson, Leigh <Leigh.Anderson@fda.hhs.gov>; Clay, Nicholas <Nicholas.Clay@fda.hhs.gov>

Subject: RE: (b)(5) K222743 Route 92 Medical Full Length 070
Access System

Hi Naira,
I am glad to assist Nick.
-Myra

Myra Smith, M.S.
Microbiologist

Neurointerventional Devices Team
FDA/CDRH/OHT5/DHT5A
White Oak/ Bldg 66/Rm 4206
10903 New Hampshire Ave
Silver Spring/ MD 20993
Phone: (301) 796-6507
myra.smith@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: Monday, September 12, 2022 12:13 PM
To: Williams, Dhanya K <Dhanya.Kumar@fda.hhs.gov>; Smith, Myra K. <Myra.Smith@fda.hhs.gov>; Anderson, Leigh <Leigh.Anderson@fda.hhs.gov>; Clay, Nicholas <Nicholas.Clay@fda.hhs.gov>
Subject: (b)(5) k222743 Route 92 Medical Full Length 070 Access System

Hi Dhanya, Leigh and Myra,

Nick will be leading the review of these two files that came in last Friday and since he's new to our devices could you please help him to get started:

(b)(5)

(b)(5)

Thank you everyone,

Naira Muradyan, PhD
Assistant Director

Neurointerventional Devices Team
DHT5A: Division of Neurosurgical, Neurointerventional & Neurodiagnostic Devices
OHT5: Office of Neurological & Physical Medicine Devices
Office of Product Evaluation and Quality
CDRH | Food and Drug Administration
White Oak, Bldg. 66 Rm 3657 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Tel: 240-402-4918
Naira.Muradyan@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>

(b)(4)

(b)(4)

510(k) Summary K222743

(b)(4)

(b)(4)

(b)(4)

(b)(4)

INSTRUCTIONS FOR USE

Route 92 Medical® Full Length 088 Access System, 132cm and 125cm and Full Length 070 Access System, 132cm

(b)(4)

(b)(4)

(b)(4)

Redlined Support Catheter Label (Pouch Label). Additions are shown in green.

(b)(4)

Redlined Delivery Catheter Label (Pouch Label). Additions are shown in green.

(b)(4)

Redlined Access System Label (Carton Label). Additions are shown in green.

(b)(4)

Sorry to bother you again, but if you could please respond to this request by COB 09/14, then it will help facilitate the next steps of our review.

From: Clay, Nicholas

Sent: Tuesday, September 13, 2022 10:14 AM

To: kirsten@r92m.com

Cc: K222743@docs.fda.gov

Subject: (b)(4)

Good morning Kirsten:

My name is Nicholas Clay, and I'm the lead reviewer for your recent 510(k) submission. As we continue our review, (b)(4)

(b)(4)

Thank you again. Please let me know if you'd like to speak further.

Nicholas E. Clay, Ph.D.

Acting Team Lead

THT5A2: Neurointerventional Devices

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

10903 New Hampshire Avenue

Silver Spring, MD 20993

nicholas.clay@fda.hhs.gov<mailto:nicholas.clay@fda.hhs.gov>

[cid:image001.png@01D8C75A.396C1BC0]<http://www.fda.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=1510&S=E>

Good Morning Nick,

(b)(4)

(b)(4)

(b)(4)

Lastly, there have been no prior submissions for this device.

Please let me know if you have any additional questions.

Many thanks,

Kirsten

From: "Clay, Nicholas" <Nicholas.Clay@fda.hhs.gov>

Date: Wednesday, September 14, 2022 at 7:22 AM

To: Kirsten Valley <kirsten@r92m.com>

Cc: "K222743@docs.fda.gov" <K222743@docs.fda.gov>

Subject: RE: [EXTERNAL] Re: (b)(4)

Good morning Kirsten:

To help facilitate our review, could you please also address the following?

(b)(4)

If you could please respond to this request by noon tomorrow (9/15), then it will help facilitate our review.

Thank you again.

-Nick

From: Kirsten Valley <kirsten@r92m.com>

Sent: Tuesday, September 13, 2022 1:43 PM

To: Clay, Nicholas <Nicholas.Clay@fda.hhs.gov>

Cc: K222743@docs.fda.gov

Subject: [EXTERNAL] Re: (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.

Hi Nicholas,

You are correct. (b)(4)

(b)(4)

Please let me know if you have any additional questions.

Many thanks,

Kirsten

Route 92 Medical

650-279-8427

From: "Clay, Nicholas" <Nicholas.Clay@fda.hhs.gov<mailto:Nicholas.Clay@fda.hhs.gov>>

Date: Tuesday, September 13, 2022 at 7:14 AM

To: Kirsten Valley <kirsten@r92m.com<mailto:kirsten@r92m.com>>

Cc: "K222743@docs.fda.gov<mailto:K222743@docs.fda.gov>" <K222743@docs.fda.gov<mailto:K222743@docs.fda.gov>>

Subject: (b)(4)

Good morning Kirsten:

My name is Nicholas Clay, and I am the lead reviewer for your recent 510(k) submission. As we continue our review, I was wondering if you could please clarify if

(b)(4)

Thank you again. Please let me know if you'd like to speak further.

Nicholas E. Clay, Ph.D.

Acting Team Lead

THT5A2: Neurointerventional Devices

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

10903 New Hampshire Avenue

Silver Spring, MD 20993

nicholas.clay@fda.hhs.gov<mailto:nicholas.clay@fda.hhs.gov>

[cid:image001.png@01D8C8D2.2A78D940]<http://www.fda.gov/>

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

https://secure-web.cisco.com/1tKip_mi4N-YTXljJUG2KrN8zro9AmTKJ-VArXXfxmKbhaac5DJbNEhxGQXfrhbnCutnmHPfw9yLU_XhX_AsjWNWA1zGSa1z8S4i7ooecFT58JnnVU0xpyUv53eRiku-FL5VXfXIXksVkcTe4kuJnppluJMfHEPtqcSnQK7e26RfceWyHEsNPSRv1BKpHYgfg/https%3A%2F%2Fwww.research.net%2F%2Fcdhrcustomerservice%3FID%3D1510%26S%3DE<https://secure-

web.cisco.com/1z-YPsQt7V18osB3zGP0Q7B5t-
jUjb6X8XhKlxGJMqSMIHdRxpQQ6DMjtgOVHKqUKf0IiuW2mrPPmemFd_24Td9txji2nfcDr6xOvuep9Fp8mD9ce
aBOZDhT-yuJ-
cnWWMieg_K28_nlcStO7CUL2y1OJFwsXOmPpz_gLG2srjug7E_vGOupWpv6rZ_bkE5gdt4cAbUsthptAHybW4-
1BHA/https%3A%2F%2Fwww.research.net%2Fs%2Fcdrhcustomerservice%3FID%3D1510%26S%3DE>

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

Date of Submission 08/20/2022	User Fee Payment ID Number (b)(4)	FDA Submission Document Number (if known)
----------------------------------	---------------------------------------------	-------------------------------------------

SECTION A TYPE OF SUBMISSION

<p>PMA & PDP</p> <input type="checkbox"/> Original <input type="checkbox"/> Modular Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Report (annual or PAS) <input type="checkbox"/> Report Amendment <input type="checkbox"/> Other: <input type="checkbox"/> Premarket Report (reprocessed SUD) <input type="checkbox"/> Licensing Agreement	<p>PMA/PDP Supplement</p> <input type="checkbox"/> 180 day - PAS protocol or labeling change, location change, trade name change <input type="checkbox"/> 180 day - Design or labeling change <input type="checkbox"/> Special CBE <input type="checkbox"/> Panel Track <input type="checkbox"/> 30-day Notice <input type="checkbox"/> Real-time Review <input type="checkbox"/> Amendment to PMA/PDP Supplement	<p>510(k)</p> <input checked="" type="checkbox"/> Original Submission: <input type="checkbox"/> Traditional <input checked="" type="checkbox"/> Special <input type="checkbox"/> Abbreviated <input type="checkbox"/> 3rd Party Traditional <input type="checkbox"/> 3rd Party Special <input type="checkbox"/> 3rd Party Abbreviated <input type="checkbox"/> Dual Track (Dual 510(k) and CLIA Waiver by Application) <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement	<p>CLIA</p> <p>CLIA Categorization Record (CR)</p> <input type="checkbox"/> Original <input type="checkbox"/> Amendment <p>CLIA Waiver by Application (CW)</p> <input type="checkbox"/> Original <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement	<p>Q-Submission</p> <input type="checkbox"/> Pre-Submission <input type="checkbox"/> Informational Meeting <input type="checkbox"/> Submission Issue Meeting <input type="checkbox"/> Day 100 Meeting <input type="checkbox"/> Agreement Meeting <input type="checkbox"/> Determination Meeting <input type="checkbox"/> Study Risk Determination <input type="checkbox"/> Other (Specify below)
<p>IDE</p> <input type="checkbox"/> Original IDE: <input type="checkbox"/> Amendment to Original IDE <input type="checkbox"/> Supplement: <input type="checkbox"/> Amendment to Supplement <input type="checkbox"/> Report: <input type="checkbox"/> Amendment to Report	<p>HDE</p> <input type="checkbox"/> Original Submission <input type="checkbox"/> Amendment to Original <input type="checkbox"/> Report <input type="checkbox"/> Report Amendment <input type="checkbox"/> HDE Supplement: <input type="checkbox"/> 75-day Supplement <input type="checkbox"/> 30-day Notice <input type="checkbox"/> Special CBE <input type="checkbox"/> Amendment to Supplement	<p>Class II Exemption Petition</p> <input type="checkbox"/> Original Submission <input type="checkbox"/> Additional Information <p>Emergency Use Authorization</p> <input type="checkbox"/> Original <input type="checkbox"/> Supplement <input type="checkbox"/> Amendment <input type="checkbox"/> Report	<p>De Novo</p> <input type="checkbox"/> Original: <input type="checkbox"/> Direct <input type="checkbox"/> Post-NSE <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement <p>Pre-Emergency Use Authorization</p> <input type="checkbox"/> Original <input type="checkbox"/> Supplement <input type="checkbox"/> Amendment	<p>Other Submission</p> <input type="checkbox"/> 513(g) <input type="checkbox"/> Appeal <input type="checkbox"/> 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 Route 92 Medical, Inc.		Establishment Registration Number/FEI (if known) 3016522967	
Street Address 155 Boyet Road, Suite 100		City San Mateo	
State/Province CA	ZIP/Postal Code 94402	Country USA	
Contact Name Kirsten Valley		Contact Title Chief Operating Officer	
Division Name (if applicable)		Phone Number (including area code) 650-279-8427	
Fax Number (including area code)		Contact Email Address kirsten@r92m.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)
- Adults and Pediatrics
- Neonate/Newborn (birth through 28 days)
- 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)
- Other (Specify below)

SECTION E PRODUCT INFORMATION – APPLICABLE TO ALL SUBMISSIONS

Trade Name	
1	Route 92 Medical Full Length 070 Access System
2	
3	
4	
5	
Common/Generic Name (Include if no Trade Name)	

SECTION F PRIOR RELATED SUBMISSIONS FOR THIS DEVICE OR STUDY

FDA document numbers of all prior related submissions (*regardless of outcome*) or state no prior submission in box 1.

1 No prior submission	2	3
4	5	6
7	8	9
10	11	12

SECTION G PRODUCT CLASSIFICATION – APPLICABLE TO ALL SUBMISSIONS

Product Code(s) (*when applicable*) (*If more than one, please separate with commas.*)

QJP (Catheter, Percutaneous, Neurovasculature)

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

<input type="checkbox"/> New Device <input type="checkbox"/> STED <input type="checkbox"/> Post-approval Study Protocol <input type="checkbox"/> HDE Request for Annual Distribution Number (ADN)	<input type="checkbox"/> Change in Design, Component, or Specification: <input type="checkbox"/> Software/Hardware <input type="checkbox"/> Color Additive <input type="checkbox"/> Material <input type="checkbox"/> Specifications <input type="checkbox"/> Other (<i>Specify below</i>)	<input type="checkbox"/> Location Change: <input type="checkbox"/> Manufacturer <input type="checkbox"/> Sterilizer <input type="checkbox"/> Packager <input type="checkbox"/> Report Submission: <input type="checkbox"/> Annual or Periodic <input type="checkbox"/> Post-approval Study
<input type="checkbox"/> Process Change: <input type="checkbox"/> Manufacturing <input type="checkbox"/> Packaging <input type="checkbox"/> Sterilization <input type="checkbox"/> Vendor/Supplier Change <input type="checkbox"/> Other (<i>Specify below</i>)	<input type="checkbox"/> Labeling Change: <input type="checkbox"/> Indications <input type="checkbox"/> Instructions <input type="checkbox"/> PAS update <input type="checkbox"/> Performance Characteristics <input type="checkbox"/> Shelf Life <input type="checkbox"/> Trade Name <input type="checkbox"/> Other (<i>Specify below</i>)	<input type="checkbox"/> Amendment: <input type="checkbox"/> Withdrawal <input type="checkbox"/> Change in Ownership <input type="checkbox"/> Change in Correspondent <input type="checkbox"/> Change of Address <input type="checkbox"/> Request for Extension <input type="checkbox"/> Response to FDA Correspondence <input type="checkbox"/> Other (<i>Specify below</i>)

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

<input type="checkbox"/> Original IDE	<input type="checkbox"/> Report: <ul style="list-style-type: none"> <input type="checkbox"/> Adverse Effect <input type="checkbox"/> Final, Study Completed <input type="checkbox"/> Annual Progress <input type="checkbox"/> Interim Progress <input type="checkbox"/> Semiannual Investigator List <input type="checkbox"/> Failure to Obtain Informed Consent <input type="checkbox"/> Compassionate Use Follow-up <input type="checkbox"/> Emergency Use <input type="checkbox"/> Live Case Follow-up <input type="checkbox"/> Completion of Patient Enrollment <input type="checkbox"/> Completion of Patient Follow-up <input type="checkbox"/> Other (<i>Specify below</i>)
<input type="checkbox"/> Supplement: <ul style="list-style-type: none"> <input type="checkbox"/> New Study/New Protocol <input type="checkbox"/> Change in Correspondent <input type="checkbox"/> Change in Manufacturer <input type="checkbox"/> Change in Sponsor <input type="checkbox"/> Change in Design <input type="checkbox"/> Change in Informed Consent <input type="checkbox"/> Change in Manufacturing <input type="checkbox"/> Change in Protocol <input type="checkbox"/> 5-Day Notice – Device or Manufacturing <input type="checkbox"/> 5-Day Notice – Protocol <input type="checkbox"/> Compassionate Use Request (under an IDE) <input type="checkbox"/> Live Case Request <input type="checkbox"/> Request Deviation from Protocol <input type="checkbox"/> Expansion of Study (Study/Sites) <input type="checkbox"/> Extension of Time to Submit Annual Report or Respond to FDA Letter 	Supplement (<i>Continued</i>) <ul style="list-style-type: none"> <input type="checkbox"/> Request for Waiver <input type="checkbox"/> IRB Certification <input type="checkbox"/> Request for CMS Recategorization <input type="checkbox"/> Study Resumed <input type="checkbox"/> Study Suspension <input type="checkbox"/> Other (<i>Specify below</i>)
<input type="checkbox"/> Amendment to Original IDE: <ul style="list-style-type: none"> <input type="checkbox"/> Amendment Before Final Decision <input type="checkbox"/> Response to Refuse to Accept <input type="checkbox"/> Response to Disapproval <input type="checkbox"/> Response to Approval with Conditions <input type="checkbox"/> Withdrawal <input type="checkbox"/> Other (<i>Specify below</i>) 	<input type="checkbox"/> Amendment to Supplement: <ul style="list-style-type: none"> <input type="checkbox"/> Response to Disapproval <input type="checkbox"/> Response to Approval with Conditions <input type="checkbox"/> Withdrawal <input type="checkbox"/> Amendment Before Final Decision (additional information) <input type="checkbox"/> Other (<i>Specify below</i>)
<input type="checkbox"/> Amendment to Report: <ul style="list-style-type: none"> <input type="checkbox"/> Response to Deficiency Letter <input type="checkbox"/> Withdrawal <input type="checkbox"/> Amendment Before Final Decision (additional information) <input type="checkbox"/> Other (<i>Specify below</i>) 	

SECTION H3

REASON FOR SUBMISSION – Q-SUBMISSION

<input type="checkbox"/> Pre-Submission: <ul style="list-style-type: none"> <input type="checkbox"/> Request Face-to-Face Meeting <input type="checkbox"/> Request Teleconference <input type="checkbox"/> Request Email Response <input type="checkbox"/> Submit Meeting Minutes <input type="checkbox"/> Request Meeting Minutes Disagreement T-con 	<input type="checkbox"/> Submission Issue Meeting: <ul style="list-style-type: none"> <input type="checkbox"/> Request Face-to-Face Meeting <input type="checkbox"/> Request Teleconference <input type="checkbox"/> Request Email Response <input type="checkbox"/> Submit Meeting Minutes <input type="checkbox"/> Request Meeting Minutes Disagreement T-con 	<input type="checkbox"/> Additional Information <ul style="list-style-type: none"> <input type="checkbox"/> Change in Legal Entity: <ul style="list-style-type: none"> <input type="checkbox"/> Change in Correspondent <input type="checkbox"/> Change in Sponsors <input type="checkbox"/> Change in Manufacturer <input type="checkbox"/> Other (<i>Specify below</i>)
<input type="checkbox"/> Agreement Meeting: <ul style="list-style-type: none"> <input type="checkbox"/> Request Face-to-Face Meeting <input type="checkbox"/> Request Teleconference 	<input type="checkbox"/> Determination Meeting: <ul style="list-style-type: none"> <input type="checkbox"/> Request Face-to-Face Meeting <input type="checkbox"/> Request Teleconference 	<input type="checkbox"/> Informational Meeting: <ul style="list-style-type: none"> <input type="checkbox"/> Request Face-to-Face Meeting <input type="checkbox"/> Request Teleconference <input type="checkbox"/> Submit Meeting Minutes <input type="checkbox"/> Request Meeting Minutes Disagreement T-Con
<input type="checkbox"/> Other (<i>Specify</i>):		

SECTION H4 REASON FOR SUBMISSION – 510(k)

<input checked="" type="checkbox"/> Original <input type="checkbox"/> Withdrawal of Original	<input type="checkbox"/> Amendment Before Final Decision: <input type="checkbox"/> Change in Ownership <input type="checkbox"/> Change in Correspondent <input type="checkbox"/> Withdrawal <input type="checkbox"/> Amendment After Final Decision	<input type="checkbox"/> Supplement: <input type="checkbox"/> Response to Refuse to Accept (RTA) <input type="checkbox"/> Response to Additional Information Request <input type="checkbox"/> Withdrawal
<input type="checkbox"/> Reprocessed SUD	<input type="checkbox"/> Corrective Action	<input type="checkbox"/> STED
<input type="checkbox"/> Third Party (Complete Section C)	<input type="checkbox"/> 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)	K210635	Route 92 Medical Full Length 088 Access System	Route 92 Medical	QJP
Predicate or Reference Device (B)	K190431	Route 92 Medical Delivery Catheter	Route 92 Medical	DQY
Predicate or Reference Device (B)				

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

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
1 <input checked="" type="checkbox"/>	8-185	Declaration of Conformity	<i>If General Use, Deviation?</i>	ASTM F451-08, standard specification for acrylic bone cement.	Section 3, p. 15
2 <input checked="" type="checkbox"/>	3-44	General Use	<i>If General Use, Deviation?</i> Yes	AAMI ANSI BP22:1994 (R) 2011 Blood Pressure Transducers	Section 4, p. 32

Entries for Utilization of Standards

	Recognition Number	Declaration of Conformity or General Use		Standards Development Organization (SDO), Designation Number-Year, and Title	Location
1 <input checked="" type="checkbox"/>	5-40	General Use	<i>If General Use, Deviation?</i> No	ISO 14971:2007 Medical devices-Applications of risk management to medical devices	p.18
2 <input checked="" type="checkbox"/>	2-258	General Use	<i>If General Use, Deviation?</i> No	ISO 10993-1:2018 Biological evaluation of medical devices- Part 1: Evaluation and testing within a risk management process	p. 16, 17, 28
3 <input checked="" type="checkbox"/>	6-408	General Use	<i>If General Use, Deviation?</i> No	ISO 10555-1:2013: Intravascular catheters- Sterile and single-use intravascular catheters- Part 1: General requirements	p.25
4 <input checked="" type="checkbox"/>	14-529	General Use	<i>If General Use, Deviation?</i> No	ISO 11135: 2014 Sterilization of health-care products-Ethylene oxide- Requirements for the development, validation and routine con	p.20

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.)

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 <input checked="" type="checkbox"/>	The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]
2 <input checked="" type="checkbox"/>	Refuse to Accept Policy for 510(k)s
3 <input checked="" type="checkbox"/>	Use of International Standard ISO 10993-1, "Biological evaluation of medical devices- Part 1: Evaluation and testing within a risk management process"
4 <input checked="" type="checkbox"/>	The Special 510(k) Program

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
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."



Food and Drug Administration
CDRH/OPEQ/OHTV/DHTVA
WO66 RM2524
10903 New Hampshire Ave
Silver Spring, MD 20993-0002

Premarket Notification 510(k) Review

Date: September 30, 2022			
Reviewer: Nicholas E. Clay, Ph.D.			
510(k)# K222743 Subject: Special			
Applicant: Route 92 Medical, Inc.		Device Trade Name: Route 92 Medical Full Length 070 Access System	
Contact Name: Kirsten Valley		Contact Title: Chief Operating Officer	
Correspondent Firm: Route 92 Medical, Inc.		Phone: (650) 279-8427 Email: kirsten@r92m.com	
Received Date: September 9, 2022		Due Date: October 9, 2022	
Pro Code(s): QJP Class: II Reg #: 870.1250		Reg Name: Percutaneous Catheter	
Predicate Devices:			
Submission #	Pro Code	Device Trade Name	Applicant
K210635	QJP	Route 92 Medical Full Length 088 Access System	Route 92 Medical Inc.

(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)

(b)(5)

(b)(5)

Digital Signature Concurrence Table (Doc ID: 04500.15.01)

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

Nicholas Clay-S

Thank you for your rapid reply, Kirsten. If we have any other questions, I'll let you know.

From: Kirsten Valley <kirsten@r92m.com>
Sent: Tuesday, September 13, 2022 1:43 PM
To: Clay, Nicholas <Nicholas.Clay@fda.hhs.gov>
Cc: K222743@docs.fda.gov
Subject: [EXTERNAL] Re: (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.

Hi Nicholas,

You are correct. (b)(4)

Please let me know if you have any additional questions.

Many thanks,
Kirsten
Route 92 Medical
650-279-8427

From: "Clay, Nicholas" <Nicholas.Clay@fda.hhs.gov>
Date: Tuesday, September 13, 2022 at 7:14 AM
To: Kirsten Valley <kirsten@r92m.com>
Cc: "K222743@docs.fda.gov" <K222743@docs.fda.gov>
Subject: (b)(4)

Good morning Kirsten:

My name is Nicholas Clay, and I'm the lead reviewer for your recent 510(k) submission. As we continue our review, I was wondering if you could please clarify if (b)(4)

Thank you again. Please let me know if you'd like to speak further.

Nicholas E. Clay, Ph.D.
Acting Team Lead

THSA2: Neurointerventional Devices
DHTSA: Division of Neurosurgical, Neurointerventional and Neurodiagnostic Devices
OHTA: Office of Neurological and Physical Medicine Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health
10963 New Hampshire Avenue
Silver Spring, MD 20992

nicholas.clay@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=1510&S=E>

Indications for Use

510(k) Number (if known)
K222743

Device Name
Route 92 Medical Full Length 070 Access System

Indications for Use (Describe)

The Route 92 Medical Full Length 070 Access System is indicated for use with compatible guide catheters in facilitating the insertion and guidance of microcatheters into a selected blood vessel in the neurovascular system.

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."

ROUTE 92 MEDICAL

155 Bovet Road, Suite 100
SAN MATEO, CA 94402
E-Mail: INFO@R92M.COM
Web: R92M.COM



September 8, 2022
Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Regulation Number: 21 CFR 870.1250
Regulation Name: Neurovascular Percutaneous Catheter
Regulation Class: Class II
Panel: Neurology
Product Code: QJP

Re: Special 510(k) for Route 92 Medical Full Length 070 Access System, Device Modification to K210635 (Route 92 Medical Full Length 088 Access System)

Dear 510(k) Review Team:

Route 92 Medical is submitting the enclosed **Special 510(k)** notification to request clearance for a change to the Route 92 Medical Full Length 088 Access System cleared under K210635. The modified device, the Route 92 Medical Full Length 070 Access System, is being manufactured and submitted by the manufacturer authorized to market the existing, unmodified device.

The Indications for Use of the modified device are unchanged from the predicate, legally marketed device. Like the previously cleared Route 92 Medical Full Length 088 Access System (K210635), the modified device, the Route 92 Medical Full Length 070 Access System, is indicated for use with compatible guide catheters in facilitating the insertion and guidance of microcatheters into a selected blood vessel in the neurovascular system, and is provided for single use and by prescription use only. In addition, the fundamental scientific technology of the modified device is unchanged from the legally marketed device. Well-established methods have been used to evaluate the change and summary-level performance data conducted under design validation (21 CFR 820.30(g)) have been submitted in accordance with the Special 510(k) provisions. There have been no prior submissions for this device.

Route 92 Medical considers our intent to market this device as confidential commercial information and requests that it be treated as such by FDA per 21 CFR 807.95. The company has taken reasonable precautions to protect this confidentiality.

Thank you in advance for your consideration of this application. Please direct any questions or requests for additional information to me at the below phone number or by electronic mail.

Sincerely,

(b)(6)

Kirsten Valley
Chief Operating Officer
Route 92 Medical, Inc.
Phone: (650)-279-8427
Email: kirsten@r92m.com

Included: one (1) eCopy of Special 510(k)



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) #: K222743 Date Received by DCC: Sep 9, 2022

Lead Reviewer: Nicholas E. Clay

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.	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Comments:		
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 continue with the additional Special 510(k) factors.</i>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Comments:		
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>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
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	<input checked="" type="checkbox"/>	<input type="checkbox"/>	001,1
2) Each section is labeled (e.g., headings or tabs designating Device Description section, Labeling section, etc.)	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
3) All pages of the submission are numbered.	<input type="checkbox"/>	<input checked="" type="checkbox"/>	
4) Type of 510(k) is identified (i.e., Traditional, Abbreviated, or Special)	<input checked="" type="checkbox"/>	<input type="checkbox"/>	

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. <small>Records processed under FOIA Request 2023-10463; Released by CDRH on 08-15-2024</small> *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	N/A	Comment	*Page #
A. Administrative					
1) All content used to support the submission is written in English (including translations of test reports, literature articles, etc.)	<input checked="" type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	
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):				<input type="checkbox"/>	
a) Device trade/proprietary name	<input checked="" type="checkbox"/>	<input type="checkbox"/>			3514, 2
b) Device class and panel OR Classification regulation OR Statement that device has not been classified with rationale for that conclusion	<input checked="" type="checkbox"/>	<input type="checkbox"/>			3514, 3
3) Submission contains an Indication for Use Statement with Rx and/or OTC designated (see also 21 CFR 801.109, and FDA's final rule, "Use of Symbols in Labeling" (81 FR 38911), available at https://www.federalregister.gov/documents/2016/06/15/2016-13989/use-of-symbols-in-labeling). See recommended format. (https://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM360431.pdf).	<input checked="" type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	3881, 1
4) Submission contains a 510(k) Summary or 510(k) Statement.	<input checked="" type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	007
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)	<input checked="" type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	005, 4
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).	<input type="checkbox"/>		<input checked="" type="checkbox"/>	<input type="checkbox"/>	
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.	<input checked="" type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	3514, 3
a) If there were prior submissions, the submitter has identified where in the current submission any issues related to a determination of substantial equivalence from prior submissions for this device are addressed.	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>		
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.	<input checked="" type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	3514, 7
a) The submission cites FDA-recognized voluntary consensus standard(s)	<input checked="" type="checkbox"/>		<input type="checkbox"/>		3514, 7

<p>Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.</p> <p>*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.</p>	Yes	No	N/A	Comment	*Page #
<p>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</p> <p>OR</p> <p>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.</p>	<input checked="" type="checkbox"/>	<input type="checkbox"/>			App C
<p>b) The submission cites non-FDA-recognized voluntary consensus standard(s)</p>	<input type="checkbox"/>		<input checked="" type="checkbox"/>		
<p>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.</p>			<input checked="" type="checkbox"/>		
<p>B. Device Description</p>					
<p>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.</p>	<input type="checkbox"/>		<input checked="" type="checkbox"/>	<input type="checkbox"/>	
<p>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).</p>	<input checked="" type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	
<p>13) The submission includes descriptive information for the device, including the following:</p>				<input type="checkbox"/>	
<p>a) A description of the principle of operation or mechanism of action for achieving the intended effect.</p>	<input checked="" type="checkbox"/>	<input type="checkbox"/>			005, 5
<p>b) A description of proposed conditions of use, such as surgical technique for implants; anatomical location of use; user interface; how the device interacts with other devices; and/or how the device interacts with the patient.</p>	<input checked="" type="checkbox"/>	<input type="checkbox"/>			005, 7
<p>c) A list and description of each device for which clearance is requested.</p>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		005,5
<p>d) Submission contains representative engineering drawing(s), schematics, illustrations, photos and/or figures of the device.</p> <p>OR</p> <p>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).</p>	<input checked="" type="checkbox"/>	<input type="checkbox"/>			005, 8
<p>14) A detailed description of all device modification(s) including rationale for each modification.</p> <p><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></p>	<input checked="" type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	005, 8-9
<p>15) Device is intended to be marketed with accessories and/or as part of a system.</p>	<input type="checkbox"/>		<input checked="" type="checkbox"/>	<input type="checkbox"/>	005, 7

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 2023-10463; Released by CDRH on 08-15-2024

*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 #

C. Substantial Equivalence Discussion

16) Submitter has identified a predicate device(s), including the following information:				<input checked="" type="checkbox"/>	
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 documenting preamendment status is available online. (https://www.fda.gov/medical-devices/quality-and-compliance-medical-devices/preamendment-status)</i>	<input checked="" type="checkbox"/>	<input type="checkbox"/>			
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).	<input checked="" type="checkbox"/>	<input type="checkbox"/>			

Comments:

(b)(4)

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 "The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]," 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>				<input type="checkbox"/>	
a) Indications for Use	<input checked="" type="checkbox"/>	<input type="checkbox"/>			005, 10
b) Technology, including technical specifications, features, materials, and principles of operation	<input checked="" type="checkbox"/>	<input type="checkbox"/>			005, 10

D. Design Control Activities

18) Design Control Activities Summary includes all of the following:				<input type="checkbox"/>	
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.	<input checked="" type="checkbox"/>	<input type="checkbox"/>			005, 17
b) Identification of the device change(s).	<input checked="" type="checkbox"/>	<input type="checkbox"/>			005, 18
c) Identification of all risks associated with each device change, including identification of risks that are considered new because of the change; and.	<input checked="" type="checkbox"/>	<input type="checkbox"/>			005, 18
d) Risk control measures to mitigate identified risks (e.g., labeling, verification).	<input checked="" type="checkbox"/>	<input type="checkbox"/>			005, 18
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 number.	<input checked="" type="checkbox"/>	<input type="checkbox"/>			005, 17

Questions and comments: PMA/OC/DR/DC/CE/DID at CDRH-FOI STATUS@fda.hhs.gov or 301-796-8118

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	N/A	Comment	*Page #
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.	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		005, 17
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.	<input checked="" type="checkbox"/>	<input type="checkbox"/>			App C
E. Proposed Labeling (see also 21 CFR part 801 and 809 as applicable)					
19) Submission includes proposed package labels and labeling (e.g., instructions for use, package insert, operator's manual).	<input checked="" type="checkbox"/>	<input type="checkbox"/>		<input checked="" type="checkbox"/>	Apps D
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>	<input checked="" type="checkbox"/>	<input type="checkbox"/>			
Comments: (b)(4)					

Digital Signature Concurrence Table

Records processed under FOIA Request 2023-10463; Released by CDRH on 08-15-2024

Nicholas Clay
-S
Digitally signed by
Nicholas Clay -S
Date: 2022.09.15 15:12:12
-04'00'

Reviewer Sign-Off

Management Sign-Off
(digital signature
optional)*

--

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

INSTRUCTIONS FOR USE

(b)(4)

(b)(4)



Build Correspondence

Convert to PDF

October 4, 2022

Route 92 Medical
Kirsten Valley
Chief Operating Officer
155 Bovet Road, Suite 100
San Mateo, California 94402

Re: K222743

Trade/Device Name: Route 92 Medical Full Length 070 Access System
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: QJP
Dated: September 8, 2022
Received: September 9, 2022

Dear Kirsten Valley:

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/pmnmn.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

Sorry to bother you again, but if you could please respond to this request by **COB 09/14**, then it will help facilitate the next steps of our review.

From: Clay, Nicholas
Sent: Tuesday, September 13, 2022 10:14 AM
To: kirsten@r92m.com
Cc: K222743@docs.fda.gov
Subject: (b)(4)

Good morning Kirsten:

My name is Nicholas Clay, and I'm the lead reviewer for your recent 510(k) submission. As we continue our review, I was wondering if you could please clarify if (b)(4)

Thank you again. Please let me know if you'd like to speak further.

Nicholas E. Clay, Ph.D.
Acting Team Lead

THSA2: Neurointerventional Devices
DHTSA: Division of Neurosurgical, Neurointerventional and Neurodiagnostic Devices
OHTS: Office of Neurological and Physical Medicine Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health
16903 New Hampshire Avenue
Silver Spring, MD 20993

nicholas.clay@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=1510&S=E>

From: [Williams, Dhanya K](#)
To: [Anderson, Leigh](#); [Muradyan, Naira](#); [Smith, Myra K.](#); [Clay, Nicholas](#)
Cc: [Williams, Dhanya K](#)
Subject: RE: [REDACTED] (b)(5) K222743 Route 92 Medical Full Length 070 Access System
Date: Thursday, September 15, 2022 9:21:51 AM
Attachments: [image001.png](#)

Hi Leigh,

Thanks very much for your note. Nick – with Leigh’s confirmation: [REDACTED] (b)(5)

[REDACTED] (b)(5)

Dhanya

From: Anderson, Leigh <Leigh.Anderson@fda.hhs.gov>
Sent: Wednesday, September 14, 2022 9:57 PM
To: Williams, Dhanya K <Dhanya.Kumar@fda.hhs.gov>; Muradyan, Naira <Naira.Muradyan@fda.hhs.gov>; Smith, Myra K. <Myra.Smith@fda.hhs.gov>; Clay, Nicholas <Nicholas.Clay@fda.hhs.gov>
Subject: RE: [REDACTED] (b)(5) K222743 Route 92 Medical Full Length 070 Access System

Hi Nick and Dhanya,

[REDACTED] (b)(5)

Thanks
Leigh

Leigh Anderson (she/her/hers)
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: Williams, Dhanya K <Dhanya.Kumar@fda.hhs.gov>

Sent: Monday, September 12, 2022 12:40 PM

To: Muradyan, Naira <Naira.Muradyan@fda.hhs.gov>; Smith, Myra K. <Myra.Smith@fda.hhs.gov>; Anderson, Leigh <Leigh.Anderson@fda.hhs.gov>; Clay, Nicholas <Nicholas.Clay@fda.hhs.gov>

Cc: Williams, Dhanya K <Dhanya.Kumar@fda.hhs.gov>

Subject: RE: [REDACTED] (b)(5) K222743 Route 92 Medical Full Length 070 Access System

Hi Nick,

First, welcome to our team! I'm looking forward to working with you.

I took a look and here are my thoughts for the two files Naira described below:

(b)(5)

(b)(5)

Feel free to email or IM me with any other questions.

Thanks,
Dhanya

From: Muradyan, Naira <Naira.Muradyan@fda.hhs.gov>

Sent: Monday, September 12, 2022 12:13 PM

To: Williams, Dhanya K <Dhanya.Kumar@fda.hhs.gov>; Smith, Myra K. <Myra.Smith@fda.hhs.gov>;
Anderson, Leigh <Leigh.Anderson@fda.hhs.gov>; Clay, Nicholas <Nicholas.Clay@fda.hhs.gov>

Subject: (b)(5) K222743 Route 92 Medical Full
Length 070 Access System

Hi Dhanya, Leigh and Myra,

Nick will be leading the review of these two files that came in last Friday and since he's new to our devices could you please help him to get started:

(b)(5)

Thank you everyone,

Naira Muradyan, PhD
Assistant Director

Neurointerventional Devices Team
DHT5A: Division of Neurosurgical, Neurointerventional & Neurodiagnostic Devices
OHT5: Office of Neurological & Physical Medicine Devices
Office of Product Evaluation and Quality
CDRH | Food and Drug Administration
White Oak, Bldg. 66 Rm 3657 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Tel: 240-402-4918
Naira.Muradyan@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: [Smith, Myra K.](#)
To: [Clay, Nicholas](#)
Subject: RE: (b)(5) Route 92 Medical Full Length 070 Access System
Date: Thursday, September 15, 2022 2:51:05 PM
Attachments: [image001.png](#)
[image007.png](#)
[image008.png](#)
[image009.png](#)

(b)(5)

-Myra

Myra Smith, M.S.
Microbiologist

Neurointerventional Devices Team
FDA/CDRH/OHT5/DHT5A
White Oak/ Bldg 66/Rm 4206
10903 New Hampshire Ave
Silver Spring/ MD 20993
Phone: (301) 796-6507
myra.smith@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: Clay, Nicholas <Nicholas.Clay@fda.hhs.gov>
Sent: Thursday, September 15, 2022 2:47 PM
To: Smith, Myra K. <Myra.Smith@fda.hhs.gov>
Subject: RE: (b)(5) K222743 Route 92 Medical Full Length 070 Access System

Hello there Myra:

Thank you again for your email. For K222743, it is my understanding that you concur with the sponsor's

(b)(5)

Thank you again.

-Nick

From: Smith, Myra K. <Myra.Smith@fda.hhs.gov>
Sent: Monday, September 12, 2022 5:12 PM
To: Clay, Nicholas <Nicholas.Clay@fda.hhs.gov>
Subject: RE: (b)(5) K222743 Route 92 Medical Full Length 070

Access System

Hi Nick,

(b)(5)

Myra Smith, M.S.
Microbiologist

Neurointerventional Devices Team
FDA/CDRH/OHT5/DHT5A
White Oak/ Bldg 66/Rm 4206
10903 New Hampshire Ave
Silver Spring/ MD 20993
Phone: (301) 796-6507
myra.smith@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: Clay, Nicholas <Nicholas.Clay@fda.hhs.gov>
Sent: Monday, September 12, 2022 1:59 PM
To: Smith, Myra K. <Myra.Smith@fda.hhs.gov>
Subject: RE: (b)(5) K222743 Route 92 Medical Full Length 070
Access System

Good afternoon Myra:

Thank you for your message. I look forward to working with you on these and other submissions.

(b)(5)

(b)(5)

Thank you again.

-Nick

From: Smith, Myra K. <Myra.Smith@fda.hhs.gov>

Sent: Monday, September 12, 2022 12:18 PM

To: Muradyan, Naira <Naira.Muradyan@fda.hhs.gov>; Williams, Dhanya K <Dhanya.Kumar@fda.hhs.gov>; Anderson, Leigh <Leigh.Anderson@fda.hhs.gov>; Clay, Nicholas <Nicholas.Clay@fda.hhs.gov>

Subject: RE: [REDACTED] (b)(5) [REDACTED] K222743 Route 92 Medical Full Length 070 Access System

Hi Naira,
I am glad to assist Nick.
-Myra

Myra Smith, M.S.
Microbiologist

Neurointerventional Devices Team
FDA/CDRH/OHT5/DHT5A
White Oak/ Bldg 66/Rm 4206
10903 New Hampshire Ave
Silver Spring/ MD 20993
Phone: (301) 796-6507
myra.smith@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: Monday, September 12, 2022 12:13 PM
To: Williams, Dhanya K <Dhanya.Kumar@fda.hhs.gov>; Smith, Myra K. <Myra.Smith@fda.hhs.gov>; Anderson, Leigh <Leigh.Anderson@fda.hhs.gov>; Clay, Nicholas <Nicholas.Clay@fda.hhs.gov>
Subject: [REDACTED] K222743 Route 92 Medical Full Length 070 Access System

Hi Dhanya, Leigh and Myra,

Nick will be leading the review of these two files that came in last Friday and since he's new to our devices could you please help him to get started:

(b)(5)

(b)(5)

Thank you everyone,

Naira Muradyan, PhD
Assistant Director

Neurointerventional Devices Team
DHT5A: Division of Neurosurgical, Neurointerventional & Neurodiagnostic Devices
OHT5: Office of Neurological & Physical Medicine Devices
Office of Product Evaluation and Quality
CDRH | Food and Drug Administration
White Oak, Bldg. 66 Rm 3657 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Tel: 240-402-4918
Naira.Muradyan@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>

(b)(4)

(b)(4)

From: [Anderson, Leigh](#)
To: [Clay, Nicholas](#)
Subject: RE: [EXTERNAL] Re: Additional Questions Regarding K222743
Date: Wednesday, September 28, 2022 11:38:11 AM
Attachments: [image001.png](#)

Hi Nick,

Thanks for checking with the company and getting more information.

I think considering their rationale, it is likely reasonable that they

(b)(5)

(b)(5)

Thanks
Leigh

From: Clay, Nicholas <Nicholas.Clay@fda.hhs.gov>
Sent: Wednesday, September 28, 2022 11:29 AM
To: Anderson, Leigh <Leigh.Anderson@fda.hhs.gov>
Subject: FW: [EXTERNAL] Re: Additional Questions Regarding K222743

Good morning Leigh:

Thank you for the ad hoc discussion yesterday. The sponsor offered the following explanation for

(b)(5)

From: Kirsten Valley <kirsten@r92m.com>
Sent: Wednesday, September 28, 2022 11:19 AM
To: Clay, Nicholas <Nicholas.Clay@fda.hhs.gov>
Cc: K222743@docs.fda.gov
Subject: Re: [EXTERNAL] Re: Additional Questions Regarding K222743

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.

Hi Nick,

Attached please find our responses to your questions. Also attached is an updated **(b)(4)**
(b)(4)

Please let me know if you have any additional questions.

Many thanks,
Kirsten

Route 92 Medical
650-279-8427

From: "Clay, Nicholas" <Nicholas.Clay@fda.hhs.gov>
Date: Tuesday, September 27, 2022 at 4:19 PM
To: Kirsten Valley <kirsten@r92m.com>
Cc: "K222743@docs.fda.gov" <K222743@docs.fda.gov>
Subject: RE: [EXTERNAL] Re: Additional Questions Regarding K222743

Thank you for your response, Kirsten. I was hoping you could please address the following as well:

(b)(4)

needed?

If you could please respond by noon Eastern on Wednesday (09/28), then it will help facilitate our review. If possible, please kindly confirm acceptance of this email at your earliest convenience.

Thank you again.

-Nick

From: Kirsten Valley <kirsten@r92m.com>
Sent: Sunday, September 25, 2022 10:55 AM
To: Clay, Nicholas <Nicholas.Clay@fda.hhs.gov>
Cc: K222743@docs.fda.gov
Subject: [EXTERNAL] Re: Additional Questions Regarding K222743

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.

Hello Nick,

Attached, please find the responses to your questions. Please let me know if you have any additional questions.

Many thanks,
Kirsten

Route 92 Medical
650-279-8427

From: "Clay, Nicholas" <Nicholas.Clay@fda.hhs.gov>
Date: Thursday, September 22, 2022 at 9:19 PM
To: Kirsten Valley <kirsten@r92m.com>
Cc: "K222743@docs.fda.gov" <K222743@docs.fda.gov>
Subject: Additional Questions Regarding K222743

Good afternoon Kirsten:

As we continue our review of K222743, I was wondering if you could please answer the following questions:

(b)(4)

(b)(4)

If you could please respond to this request by **9 am (Eastern) on 09/26**, then it will help facilitate our review.

Please let me know if you want to discuss further. Thank you again.

Nicholas E. Clay, Ph.D.

Acting Team Lead

THT5A2: Neurointerventional Devices
DHT5A: Division of Neurosurgical, Neurointerventional and Neurodiagnostic Devices
OHTS: Office of Neurological and Physical Medicine Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health
10903 New Hampshire Avenue
Silver Spring, MD 20993

nicholas.clay@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=1510&S=E>

From: [Clay, Nicholas](#)
To: [Anderson, Leigh](#)
Subject: RE: Question on: (b)(5) for K222743
Date: Thursday, September 29, 2022 10:25:00 AM
Attachments: [image001.png](#)
[image002.png](#)
[image003.png](#)

Thank you for offering your perspective again, Leigh. I greatly appreciate it.

From: Anderson, Leigh <Leigh.Anderson@fda.hhs.gov>
Sent: Thursday, September 29, 2022 9:11 AM
To: Clay, Nicholas <Nicholas.Clay@fda.hhs.gov>
Subject: RE: Question on: (b)(5) for K222743

Hi Nick,

Sure, no problem. Fair question.

(b)(5)

Thanks
Leigh

From: Clay, Nicholas <Nicholas.Clay@fda.hhs.gov>
Sent: Wednesday, September 28, 2022 8:42 PM
To: Anderson, Leigh <Leigh.Anderson@fda.hhs.gov>
Subject: Question on: (b)(5) for K222743

Good evening Leigh:

(b)(5)

(b)(5)

I understand you have a high workload, but I greatly appreciate your help in getting me up to speed. Thank you again.

Nicholas E. Clay, Ph.D.

Acting Team Lead

THSA2: Neurointerventional Devices
DHSA: Division of Neurosurgical, Neurointerventional and Neurodiagnostic Devices
OHTS: Office of Neurological and Physical Medicine Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health
10903 New Hampshire Avenue
Silver Spring, MD 20993

nicholas.clay@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=1510&S=F>

(b)(4)

(b)(4)

APPENDIX E: Proposed Labels, Modified Device

- LBL 2086, Pouch Label, Full Length 070 Support Catheter
- LBL 0473, Pouch Label, Tenzing 7 Delivery Catheter (070 Delivery Catheter)
- LBL 2088, Shelf Carton Label, Full Length 070 Access System

LBL 2086, Pouch Label, Full Length 070 Support Catheter

(b)(4)

LBL 0473, Pouch Label, Tenzing 7 Delivery Catheter

(b)(4)

LBL 2088, Shelf Carton Label, Full Length 070 Access System

(b)(4)

Thank you for providing clarification, Kirsten.

From: Kirsten Valley <kirsten@r92m.com>
Sent: Thursday, September 15, 2022 10:10 AM
To: Clay, Nicholas <Nicholas.Clay@fda.hhs.gov>
Cc: K222743@docs.fda.gov
Subject: Re: [EXTERNAL] Re: (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 Nick,

(b)(4)

Please let me know if you have any additional questions.

Many thanks,
Kirsten

From: "Clay, Nicholas" <Nicholas.Clay@fda.hhs.gov>
Date: Wednesday, September 14, 2022 at 7:22 AM
To: Kirsten Valley <kirsten@r92m.com>
Cc: "K222743@docs.fda.gov" <K222743@docs.fda.gov>
Subject: RE: [EXTERNAL] Re: (b)(4)

Good morning Kirsten:

To help facilitate our review, could you please also address the following?

(b)(4)

If you could please respond to this request by noon tomorrow (9/15), then it will help facilitate our review.

Thank you again.

-Nick

From: Kirsten Valley <kirsten@r92m.com>
Sent: Tuesday, September 13, 2022 1:43 PM
To: Clay, Nicholas <Nicholas.Clay@fda.hhs.gov>
Cc: K222743@docs.fda.gov
Subject: [EXTERNAL] Re: (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.

Hi Nicholas,

(b)(4)

Please let me know if you have any additional questions.

Many thanks,
Kirsten
Route 92 Medical
650-279-8427

From: "Clay, Nicholas" <Nicholas.Clay@fda.hhs.gov>
Date: Tuesday, September 13, 2022 at 7:14 AM
To: Kirsten Valley <kirsten@r92m.com>
Cc: "K222743@docs.fda.gov" <K222743@docs.fda.gov>
Subject: (b)(4)

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

Good morning Kirsten:

My name is Nicholas Clay, and I'm the lead reviewer for your recent 510(k) submission. As we continue our review, I was wondering if you could please clarify if

(b)(4)

Thank you again. Please let me know if you'd like to speak further.

Nicholas E. Clay, Ph.D.

Acting Team Lead

TH TSA2: Neurointerventional Devices
DH TSA: Division of Neurosurgical, Neurointerventional and Neurodiagnostic Devices
OHTS: Office of Neurological and Physical Medicine Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health
16903 New Hampshire Avenue
Silver Spring, MD 20993

nicholas.clay@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=1510&S=E>

From: DCCLetters@fda.hhs.gov [DCCLetters@fda.hhs.gov]
Sent: 9/9/2022 8:58:27 PM
To: kirsten@r92m.com
CC: DCCLetters@fda.hhs.gov
Subject: K222743 Acknowledgement Letter
Attachments: K222743-Acknowledgement Letter.pdf

September 9, 2022

Thank you for your submission. We have attached your acknowledgement letter for your records. If you have any questions about your acknowledgement letter, please contact us at DCCmailroom@fda.hhs.gov. Please do not reply to this email.

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



**U.S. FOOD & DRUG
ADMINISTRATION**

Records processed under FOIA Request 2023-10463; Released by CDRH on 08-15-2024

Acknowledgement Letter

09/09/2022

Kirsten Valley, Chief Operating Officer
Route 92 Medical, Inc.
155 Bovet Road, Suite 100
San Mateo, CA 94402
UNITED STATES

Dear Kirsten Valley:

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: K222743

Received: 09/09/2022

Applicant: Route 92 Medical, Inc.

Device: Route 92 Medical Full Length 070 Access System

We will notify you when the review of this submission document has been completed or if any additional information is required. If you are submitting new information about a submission for which we have already made a final decision, please note that your submission will not be re-opened. 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

October 4, 2022</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, Nicholas Clay.</p>

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

Hello Nick,

Attached, please find the responses to your questions. Please let me know if you have any additional questions.

Many thanks,

Kirsten

Route 92 Medical

650-279-8427

From: "Clay, Nicholas" <Nicholas.Clay@fda.hhs.gov>

Date: Thursday, September 22, 2022 at 9:19 PM

To: Kirsten Valley <kirsten@r92m.com>

Cc: "K222743@docs.fda.gov" <K222743@docs.fda.gov>

Subject: Additional Questions Regarding K222743

Good afternoon Kirsten:

As we continue our review of K222743, I was wondering if you could please answer the following questions:

(b)(4)

If you could please respond to this request by 9 am (Eastern) on 09/26, then it will help facilitate our review.

Please let me know if you want to discuss further. Thank you again.

Nicholas E. Clay, Ph.D.

Acting Team Lead

THT5A2: Neurointerventional Devices

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

10903 New Hampshire Avenue

Silver Spring, MD 20993

nicholas.clay@fda.hhs.gov<mailto:nicholas.clay@fda.hhs.gov>

[cid:image001.png@01D8D0FF.7AAC26D0]<http://www.fda.gov/>

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

https://secure-web.cisco.com/1loX9os_JiSe2bpZ3hFBsKHyx-dUF9UhfxyNrec73-vehj9Cnvof5xAS9ZpXpZQT9OZfQ9i1zirYsgBmHQ0VGXKTlg0ExNkooLB2py0spBm4lnhWYxWrFHprKUw1Ozgr9Mx26jr9cQqOLXB01lEOXIYZnRTXTZ7lx-1ovu34rTwT3-LoakqEq6H2LLa70MWUj-XSJPLj3qys5gDy4XUvfsg/https%3A%2F%2Fwww.research.net%2Fs%2Fcdrhcustomerservice%3FID%3D1510%26S%3DE

September 15, 2022</br></br>

Acceptance Review Notification - Accepted

<p>An administrative acceptance review was conducted on your submission K222743, 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, Nicholas Clay. 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>

Good afternoon Kirsten:

Thank you for previously participating in IR for this submission

(b)(4)

Please let me know if you'd like to speak further. Thank you again.

Nicholas E. Clay, Ph.D.

Acting Team Lead

THSTA: Neurointerventional Devices
DHTSA: Division of Neurosurgical, Neurointerventional and Neurodiagnostic Devices
OHTS: Office of Neurological and Physical Medicine Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health
10903 New Hampshire Avenue
Silver Spring, MD 20993

nicholas.clay@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=1510&S=E>

Hi Nicholas,

(b)(4)

Please let me know if you have any additional questions.

Many thanks,
Kirsten
Route 92 Medical
650-279-8427

From: "Clay, Nicholas" <Nicholas.Clay@fda.hhs.gov>
Date: Tuesday, September 13, 2022 at 7:14 AM
To: Kirsten Valley <kirsten@r92m.com>
Cc: "K222743@docs.fda.gov" <K222743@docs.fda.gov>
Subject: (b)(4)

Good morning Kirsten:

My name is Nicholas Clay, and I'm the lead reviewer for your recent 510(k) submission. As we continue our review, I was wondering if you could please clarify if

(b)(4)

Thank you again. Please let me know if you'd like to speak further.

Nicholas E. Clay, Ph.D.

Acting Team Lead

THSA2: Neurointerventional Devices
DHSA: Division of Neurosurgical, Neurointerventional and Neurodiagnostic Devices
OHTS: Office of Neurological and Physical Medicine Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health
10903 New Hampshire Avenue
Silver Spring, MD 20903

nicholas.clay@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=1510&S=E>

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.	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
Comments:				
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>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	

Contains Nonbinding Recommendations

	<i>continue with the additional Special 510(k) factors.</i>		
Comments:			
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>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Comments:			
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>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
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.

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.	<input checked="" type="checkbox"/>	<input type="checkbox"/>	p. 1
2.	Each section is labeled (e.g., headings or tabs designating Device Description section, Labeling section, etc.).	<input checked="" type="checkbox"/>	<input type="checkbox"/>	Section ii, Cover Letter
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</i>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	Throughout

Contains Nonbinding Recommendations

	(e.g., 12-1, 12-2...).			
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>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	Section ii, Cover Letter
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 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.		Yes	No	N/A	*Page #
*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.					
A.	Administrative				
1.	All content used to support the submission is written in English (including translations of test reports, literature articles, etc.).	<input checked="" type="checkbox"/>	<input type="checkbox"/>		
Comments:					
2.	Submission identifies the following (FDA recommends use of the CDRH Premarket Review Submission Cover Sheet form (<u>Form 3514</u> , available at https://www.fda.gov/media/72421/download):				
	a. Device trade/proprietary name	<input checked="" type="checkbox"/>	<input type="checkbox"/>		Section ii
	b. Device class and panel OR Classification regulation OR Statement that device has not been classified with rationale for that conclusion	<input checked="" type="checkbox"/>	<input type="checkbox"/>		Section ii
Comments:					
3.	Submission contains an Indications for Use Statement with Rx	<input checked="" type="checkbox"/>	<input type="checkbox"/>		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.		Yes	No	N/A	*Page #
*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.					
	and/or OTC designated (see also 21 CFR 801.109, and FDA's final rule, " Use of Symbols in Labeling " (81 FR 38911), available at https://www.federalregister.gov/documents/2016/06/15/2016-13989/use-of-symbols-in-labeling). <i>See recommended format (https://www.fda.gov/media/86323/download).</i>				
	Comments:				
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>	<input checked="" type="checkbox"/>	<input type="checkbox"/>		p. 3
	Comments:				
5.	Submission contains a Truthful and Accuracy Statement per 21 CFR 807.87(l). <i>See recommended format (https://www.fda.gov/medical-devices/premarket-notification-510k/premarket-notification-truthful-and-accurate-statement).</i>	<input checked="" type="checkbox"/>	<input type="checkbox"/>		p. 4
	Comments:				
6.	Submission is a Class III 510(k) Device. <i>Select "N/A" only if submission is not a Class III 510(k).</i>	<input type="checkbox"/>		<input checked="" type="checkbox"/>	
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>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	
	Comments				
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.). <u>OR</u> States that there were no prior submissions for the subject device.	<input checked="" type="checkbox"/>	<input type="checkbox"/>		Section ii, Cover Letter

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.		Yes	No	N/A	*Page #
*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.					
	<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.	<p>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.</p> <p><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></p> <p><i>Select "N/A" if the submitter states there were no prior submissions.</i></p>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	
Comments:					
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>	<input checked="" type="checkbox"/>		<input type="checkbox"/>	
a.	The submission cites FDA-recognized voluntary consensus standard(s).	<input checked="" type="checkbox"/>		<input type="checkbox"/>	p. 15, 16, 18, 23

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 #
		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.	<input checked="" type="checkbox"/>	<input type="checkbox"/>		p.15,16,18, 23
		b.	The submission cites non-FDA-recognized voluntary consensus standard(s).	<input type="checkbox"/>		<input checked="" type="checkbox"/>	
		i.	The basis of use is included along with the underlying information or data that supports how the standard was used.	<input type="checkbox"/>	<input type="checkbox"/>		
			Comments:				
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.						<input checked="" type="checkbox"/>	
9.	Submission identifies the product as a combination product.			<input type="checkbox"/>	<input type="checkbox"/>		
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.			<input type="checkbox"/>		<input type="checkbox"/>	

Section ii. Cover Letter

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. The submission includes appropriate patent statement or certification and a statement that the submitter will give notice, as applicable. See section 503(g)(5)(A)&(C) of the FD&C Act.	<input type="checkbox"/>	<input type="checkbox"/>		
	Comments:				
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>	<input type="checkbox"/>		<input checked="" type="checkbox"/>	
	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>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	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. OR 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</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

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.		Yes	No	N/A	*Page #
*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.					
<i>information or any alternative approach as outlined above. Note that the adequacy of how such mitigation measures have been addressed should be assessed during the substantive review.</i>					
Comments:					
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).	<input checked="" type="checkbox"/>	<input type="checkbox"/>		Section 4, Section 6, Appendix D, Appendix E
Comments:					
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.	<input checked="" type="checkbox"/>	<input type="checkbox"/>		pp. 5,8
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.	<input checked="" type="checkbox"/>	<input type="checkbox"/>		pp. 5-9
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>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	pp. 8-9
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>	<input checked="" type="checkbox"/>	<input type="checkbox"/>		pp. 8-9

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.		Yes	No	N/A	*Page #
*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.					
Comments: Type text here					
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>	<input checked="" type="checkbox"/>	<input type="checkbox"/>		pp. 9-15
Comments:					
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>	<input type="checkbox"/>		<input checked="" type="checkbox"/>	
a.	Submission includes a list of all accessories to be marketed with the subject device.	<input type="checkbox"/>	<input type="checkbox"/>		
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>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
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.	<input type="checkbox"/>	<input type="checkbox"/>		
Comments:					
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	<input checked="" type="checkbox"/>	<input type="checkbox"/>		

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.		Yes	No	N/A	*Page #
<p>*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.</p>					
	<p>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 is available online (https://www.fda.gov/medical-devices/quality-and-compliance-medical-devices/preamendment-status)</u></i>.</p>				
	<p>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.</p>	<input checked="" type="checkbox"/>	<input type="checkbox"/>		pp 9-26, 29, Appendix B
Comments:					
17.	<p>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></p>				
	<p>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></p>	<input checked="" type="checkbox"/>	<input type="checkbox"/>		pp. 5, 9
	<p>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></p>	<input checked="" type="checkbox"/>	<input type="checkbox"/>		pp. 9-15

Section iii Cover Letter
 Page 10 of 10
 Ver Letter

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 #
			<i>FDA recommends a tabular format for comparing 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>				
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.	<input checked="" type="checkbox"/>	<input type="checkbox"/>		pp. 17-27
		b.	Identification of the device change(s).	<input checked="" type="checkbox"/>	<input type="checkbox"/>		pp. 19-26
		c.	Identification of all risks associated with each device change, including identification of risks that are considered new because of the change; and	<input checked="" type="checkbox"/>	<input type="checkbox"/>		pp. 19-26
		d.	Risk control measures to mitigate identified risks (e.g., labeling, verification).	<input checked="" type="checkbox"/>	<input type="checkbox"/>		pp. 19-26
		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.	<input checked="" type="checkbox"/>	<input type="checkbox"/>		pp. 19-26
		i.	For non-standardized test methods only: <ul style="list-style-type: none"> 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 	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	pp.19-26

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.				Yes	No	N/A	*Page #
*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.							
			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 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.		<input checked="" type="checkbox"/>	<input type="checkbox"/>		Appendix C
Comments:							
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).		<input checked="" type="checkbox"/>	<input type="checkbox"/>		p. 28, Appendix D Appendix E
	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>		<input checked="" type="checkbox"/>	<input type="checkbox"/>		Appendix D
Comments:							

Digital Signature Concurrence Table	
Reviewer Sign-Off	
Management Sign-Off (digital signature optional)*	

*Management review of checklist and concurrence with decision required.

Good morning Kirsten:

My name is Nicholas Clay, and I'm the lead reviewer for your recent 510(k) submission. As we continue our review, I was wondering if you could please clarify if:

(b)(4)

(b)(4)

Thank you again. Please let me know if you'd like to speak further.

Nicholas E. Clay, Ph.D.

Acting Team Lead

THT5A2: Neurointerventional Devices

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

10903 New Hampshire Avenue

Silver Spring, MD 20993

nicholas.clay@fda.hhs.gov<<mailto:nicholas.clay@fda.hhs.gov>>

[cid:image001.png@01D8C759.36A724D0]<<http://www.fda.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=1510&S=E>

510(k) Summary

(b)(4)

(b)(4)

(b)(4)

(b)(4)

Hi Nicholas,

(b)(4)

Please let me know if you have any additional questions.

Many thanks,

Kirsten

Route 92 Medical

650-279-8427

From: "Clay, Nicholas" <Nicholas.Clay@fda.hhs.gov>

Date: Tuesday, September 13, 2022 at 7:14 AM

To: Kirsten Valley <kirsten@r92m.com>

Cc: "K222743@docs.fda.gov" <K222743@docs.fda.gov>

Subject: **(b)(4)**

Good morning Kirsten:

My name is Nicholas Clay, and I am the lead reviewer for your recent 510(k) submission. As we continue our review, I was wondering if you could please clarify if

(b)(4)

Thank you again. Please let me know if you'd like to speak further.

Nicholas E. Clay, Ph.D.

Acting Team Lead

THT5A2: Neurointerventional Devices

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

10903 New Hampshire Avenue

Silver Spring, MD 20993

nicholas.clay@fda.hhs.gov<mailto:nicholas.clay@fda.hhs.gov>

[cid:image001.png@01D8C75D.A6619A90]<http://www.fda.gov/>

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

https://secure-web.cisco.com/1YZpRrzmmoqh5er9r-BgBRX7jv_U5Cb1LDWyJDxY2Uj29kjbFXNtNHjzQwrbc_NvovfYamkFvq0kyMqnzhhsinSP6IhZgKaKaYtfsxWQeccIECN9ftzQLiIJ6jLvdi88HlquoyzoxP1c35KYhwEhE8xAjSvfEJXvrBXuIiW6RQeO9b_pcJmocHaE3FbE-j0bnElzV6hJoHGVzyzqNkfDaQ/https%3A%2F%2Fwww.research.net%2Fs%2Fcdhrhcustomerservice%3FID%3D1510%26S%3DE

Table 5-1: Summary of Design Control Activities

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

Thank you for your response, Kirsten.

From: Kirsten Valley <kirsten@r92m.com>
Sent: Wednesday, September 28, 2022 11:19 AM
To: Clay, Nicholas <Nicholas.Clay@fda.hhs.gov>
Cc: K222743@docs.fda.gov
Subject: Re: [EXTERNAL] Re: Additional Questions Regarding K222743

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.

Hi Nick,

Attached please find our responses to your questions. Also attached is an updated

(b)(4)

Please let me know if you have any additional questions.

Many thanks,
Kirsten

Route 92 Medical
650-279-8427

From: "Clay, Nicholas" <Nicholas.Clay@fda.hhs.gov>
Date: Tuesday, September 27, 2022 at 4:19 PM
To: Kirsten Valley <kirsten@r92m.com>
Cc: "K222743@docs.fda.gov" <K222743@docs.fda.gov>
Subject: RE: [EXTERNAL] Re: Additional Questions Regarding K222743

Thank you for your response, Kirsten. I was hoping you could please address the following as well:

(b)(4)

If you could please respond by noon Eastern on Wednesday (09/28), then it will help facilitate our review. If possible, please kindly confirm acceptance of this email at your earliest convenience.

Thank you again.

-Nick

From: Kirsten Valley <kirsten@r92m.com>
Sent: Sunday, September 25, 2022 10:55 AM
To: Clay, Nicholas <Nicholas.Clay@fda.hhs.gov>
Cc: K222743@docs.fda.gov
Subject: [EXTERNAL] Re: Additional Questions Regarding K222743

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.

Hello Nick,

Attached, please find the responses to your questions. Please let me know if you have any additional questions.

Many thanks,
Kirsten

Route 92 Medical
650-279-8427

From: "Clay, Nicholas" <Nicholas.Clay@fda.hhs.gov>
Date: Thursday, September 22, 2022 at 9:19 PM
To: Kirsten Valley <kirsten@r92m.com>

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

Cc: "K222743@docs.fda.gov" <K222743@docs.fda.gov>

Subject: Additional Questions Regarding K222743

Good afternoon Kirsten:

As we continue our review of K222743, I was wondering if you could please answer the following questions:

(b)(4)

If you could please respond to this request by **9 am (Eastern) on 09/26**, then it will help facilitate our review.

Please let me know if you want to discuss further. Thank you again.

Nicholas E. Clay, Ph.D.

Acting Team Lead

THSA2: Neurointerventional Devices
DHTSA: Division of Neurosurgical, Neurointerventional and Neurodiagnostic Devices
OHTA: Office of Neurological and Physical Medicine Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health
10963 New Hampshire Avenue
Silver Spring, MD 20992

nicholas.clay@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=1510&S=E>

Hello Nick,

Attached, please find the responses to your questions. Please let me know if you have any additional questions.

Many thanks,
Kirsten

Route 92 Medical
650-279-8427

From: "Clay, Nicholas" <Nicholas.Clay@fda.hhs.gov>
Date: Thursday, September 22, 2022 at 9:19 PM
To: Kirsten Valley <kirsten@r92m.com>
Cc: "K222743@docs.fda.gov" <K222743@docs.fda.gov>
Subject: Additional Questions Regarding K222743

Good afternoon Kirsten:

As we continue our review of K222743, I was wondering if you could please answer the following questions:

(b)(4)

If you could please respond to this request by **9 am (Eastern) on 09/26**, then it will help facilitate our review.

Please let me know if you want to discuss further. Thank you again.

Nicholas E. Clay, Ph.D.
Acting Team Lead

THTSA2: Neurointerventional Devices
DHTSA: Division of Neurosurgical, Neurointerventional and Neurodiagnostic Devices
OHTS: Office of Neurological and Physical Medicine Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health
10903 New Hampshire Avenue
Silver Spring, MD 20903

nicholas.clay@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=1510&S=E>

Response to Sept 27, 2022 Email re: K222743

(b)(4)

(b)(4)



October 4, 2022

Route 92 Medical
Kirsten Valley
Chief Operating Officer
155 Bovet Road, Suite 100
San Mateo, California 94402

Re: K222743

Trade/Device Name: Route 92 Medical Full Length 070 Access System
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: QJP
Dated: September 8, 2022
Received: September 9, 2022

Dear Kirsten Valley:

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)
K222743

Device Name
Route 92 Medical Full Length 070 Access System

Indications for Use (Describe)

The Route 92 Medical Full Length 070 Access System is indicated for use with compatible guide catheters in facilitating the insertion and guidance of microcatheters into a selected blood vessel in the neurovascular system.

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
PRAStaff@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 K222743

Sponsor: Route 92 Medical
155 Bovet Road, Suite 100
San Mateo, CA 94402

Contact: Kirsten Valley
(650) 581-1179

Date Prepared: October 3, 2022

Device Name: Route 92 Medical Full Length 070 Access System

Common Name: Percutaneous Catheter

Classification Name: Catheter, Percutaneous, Neurovasculature (Product Code QJP, 21 CFR 870.1250)

Device Classification: Class II

Predicate Device: Route 92 Medical Full Length 088 Access System
K210635

Reference Device: Route 92 Medical Delivery Catheter
K190431

Device Description

The Route 92 Medical Full Length 070 Access System is comprised of a Support Catheter and a Delivery Catheter. The Support Catheter is a single-lumen, variable stiffness catheter. The Delivery Catheter is a hubbed, single-lumen variable stiffness catheter. Both catheters are hydrophilically coated. The devices are provided sterile and non-pyrogenic and are intended for single use only.

Indications for Use

The Route 92 Medical Full Length 070 Access System is indicated for use with compatible guide catheters in facilitating the insertion and guidance of microcatheters into a selected blood vessel in the neurovascular system.

Comparison to the Predicate Device

The method of action, design, and materials of the Route 92 Medical Full Length 070 Access System are equivalent to the Predicate Device as shown in the following table.

Attribute	Predicate Device Route 92 Medical Full Length 088 Access System (K210635)	Subject Device Route 92 Medical Full Length 070 Access System (K222743)
Indications for Use	The Route 92 Medical Full Length 088 Access System is indicated for use with compatible guide catheters in facilitating the insertion and guidance of microcatheters into a selected blood vessel in the neurovascular system.	The Route 92 Medical Full Length 070 Access System is indicated for use with compatible guide catheters in facilitating the insertion and guidance of microcatheters into a selected blood vessel in the neurovascular system.
Device Description	Sterile, single-use, variable stiffness, coil-reinforced catheter	Same
Targeted population	Patients requiring use of a microcatheter in the neurovascular system	Same
User	Physicians trained in neurovascular interventional techniques	Same
Anatomical Sites	Neurovasculature only	Same
Materials	Polymers and metals commonly used in the manufacture of medical devices	Same
Sterilization	100% ethylene oxide	Same
Shelf Life	8 months	6 months
Support Catheter		
Inner Diameter	0.088"	0.070"
Outer Diameter	0.101"	0.084"
Length	132 cm and 125 cm	132 cm
Delivery Catheter		
Inner Diameter	0.019"	Same
Outer Diameter	Distal: 0.080" Proximal: 0.062"	0.062"
Length	151 cm	Same

Non-Clinical Testing**Biocompatibility Testing**

The patient-contacting materials were unchanged compared to the predicate device; therefore, no additional biocompatibility testing was required.

Performance Testing

The successful completion of the performance testing listed in the following table demonstrates that the Route 92 Medical Full Length 070 Access System is suitable for its intended use.

Test	Test Method	Results
Dimensional Verification	Device dimensions were measured to confirm conformance to the specifications	PASS All samples met the pre-determined acceptance criteria
Luer Integrity	Tested per ISO 80369-7:2016	PASS All samples met the pre-determined acceptance criteria
Tensile Strength	The tensile strength of the catheter sections and bonds was tested	PASS All samples met the pre-determined acceptance criteria
Kink Resistance	Test specimen segments were formed into a defined bend diameter to evaluate kink resistance	PASS All samples met the pre-determined acceptance criteria
Torsion Resistance	The test specimens were rotated to evaluate integrity after rotation	PASS All samples met the pre-determined acceptance criteria
Tip Flexibility	Test specimens were tested for tip flexibility	PASS All samples met the pre-determined acceptance criteria
Air Leakage	Tested per ISO 10555-1:2013 Annex D.	PASS All samples met the pre-determined acceptance criteria
Liquid Leakage	Tested per ISO 10555-1:2013 Annex C.	PASS All samples met the pre-determined acceptance criteria
Static Burst	Tested per ISO 10555-1:2013 Annex F.	PASS All samples met the pre-determined acceptance criteria
Dynamic Burst	Mechanical integrity was maintained up to the specified pressures	PASS All samples met the pre-determined acceptance criteria

Test	Test Method	Results
Hydrophilic Coating Integrity	The integrity of the hydrophilic coating was evaluated after multiple insertion and withdrawal cycles.	<p style="text-align: center;">PASS</p> <p style="text-align: center;">All samples met the pre-determined acceptance criteria</p>
Simulated Use Testing	Deliverability and compatibility with accessory devices were evaluated in a neurovascular model	<p style="text-align: center;">PASS</p> <p style="text-align: center;">All samples met the pre-determined acceptance criteria</p>

Conclusions

The Route 92 Medical Full Length 070 Access System has the same intended use, the same technological characteristics and same method of action as the predicate device. Differences between the subject and predicate devices do not raise new concerns of safety and effectiveness of the device. The successful completion of performance testing demonstrates that the Route 92 Medical Full Length 070 Access System is substantially equivalent to the predicate device.

Hi Nick,

Attached please find our responses to your questions. Also attached is an updated

(b)(4)

Please let me know if you have any additional questions.

Many thanks,

Kirsten

Route 92 Medical

650-279-8427

From: "Clay, Nicholas" <Nicholas.Clay@fda.hhs.gov>

Date: Tuesday, September 27, 2022 at 4:19 PM

To: Kirsten Valley <kirsten@r92m.com>

Cc: "K222743@docs.fda.gov" <K222743@docs.fda.gov>

Subject: RE: [EXTERNAL] Re: Additional Questions Regarding K222743

Thank you for your response, Kirsten. I was hoping you could please address the following as well:

(b)(4)

If you could please respond by noon Eastern on Wednesday (09/28), then it will help facilitate our review. If possible, please kindly confirm acceptance of this email at your earliest convenience.

Thank you again.

-Nick

From: Kirsten Valley <kirsten@r92m.com>

Sent: Sunday, September 25, 2022 10:55 AM

To: Clay, Nicholas <Nicholas.Clay@fda.hhs.gov>

Cc: K222743@docs.fda.gov

Subject: [EXTERNAL] Re: Additional Questions Regarding K222743

CAUTION: This email originated from outside of the organization. Do not click links or Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

open attachments unless you recognize the sender and know the content is safe.

Hello Nick,

Attached, please find the responses to your questions. Please let me know if you have any additional questions.

Many thanks,

Kirsten

Route 92 Medical

650-279-8427

From: "Clay, Nicholas" <Nicholas.Clay@fda.hhs.gov<mailto:Nicholas.Clay@fda.hhs.gov>>

Date: Thursday, September 22, 2022 at 9:19 PM

To: Kirsten Valley <kirsten@r92m.com<mailto:kirsten@r92m.com>>

Cc: "K222743@docs.fda.gov<mailto:K222743@docs.fda.gov>"
<K222743@docs.fda.gov<mailto:K222743@docs.fda.gov>>

Subject: Additional Questions Regarding K222743

Good afternoon Kirsten:

As we continue our review of K222743, I was wondering if you could please answer the following questions:

(b)(4)

If you could please respond to this request by 9 am (Eastern) on 09/26, then it will help facilitate our review.

Please let me know if you want to discuss further. Thank you again.

Nicholas E. Clay, Ph.D.

Acting Team Lead

THT5A2: Neurointerventional Devices

DHT5A: Division of Neurosurgical, Neurointerventional and Neurodiagnostic Devices

OHT5: Office of Neurological and Physical Medicine Devices

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

Office of Product Evaluation and Quality

Center for Devices and Radiological Health

10903 New Hampshire Avenue

Silver Spring, MD 20993

nicholas.clay@fda.hhs.gov<mailto:nicholas.clay@fda.hhs.gov>

[cid:image001.png@01D8D35E.58514FA0]<http://www.fda.gov/>

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

https://secure-web.cisco.com/1JibBjtpq34_7HkNsRTw9z6vG1NjiLa9YSzWZC0-d-jpXvrnh_N8cc0isouSIIvbSXRz4W-WtxvgXaiRECLfn6l6eZWWvo24wSk4ujEzf0jvvgGKr9jpkJ_XAgCiK7JKIsv-DnymMkMPTjF1M-k49ny8Xf-LMWUG9ZZ8Q_92Cip5uwb3wEGTzwQDHPRCt8w9_hB0l6Oklyco_5YSAZsIxrJMCAQZJTSQ5cnCk1DkVPUw/https%3A%2F%2Fwww.research.net%2Fs%2Fcdrhcustomerservice%3FID%3D1510%26S%3DE<https://secure-web.cisco.com/1pafvORR1D20HswXAk5ZXSD6-7OcBYIpEFUcYXmH2BSn4h-k7De0RYKHmLz6i_11FiilU9a4LIan-83edBKZYeOiBGa-_GJ2083e7-zA1fjJK-VJgo6AziVbJ5mrhs8AGnvEB_o0RmHKMbHsClWdvgcF90Bb3naiiTT6KpW1zKgj20xUwbXBpkgaFrjrqrAzOrFWjY-dQFGarIRuOX5QJvcH4NVNAkkDx_24e5YqIhbU/https%3A%2F%2Fwww.research.net%2Fs%2Fcdrhcustomerservice%3FID%3D1510%26S%3DE>

510(k) Summary

(b)(4)

(b)(4)

(b)(4)

(b)(4)

Good afternoon Kirsten:

As we continue our review of K222743, I was wondering if you could please answer the following questions:

(b)(4)

If you could please respond to this request by 9 am (Eastern) on 09/26, then it will help facilitate our review.

Please let me know if you want to discuss further. Thank you again.

Nicholas E. Clay, Ph.D.

Acting Team Lead

THT5A2: Neurointerventional Devices

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

10903 New Hampshire Avenue

Silver Spring, MD 20993

nicholas.clay@fda.hhs.gov<mailto:nicholas.clay@fda.hhs.gov>

[cid:image001.png@01D8CE92.6083D830]<<http://www.fda.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=1510&S=E>

Good morning Kirsten:

To help facilitate our review, could you please also address the following?

(b)(4)

If you could please respond to this request by noon tomorrow (9/15), then it will help facilitate our review.

Thank you again.

-Nick

From: Kirsten Valley <kirsten@r92m.com>
Sent: Tuesday, September 13, 2022 1:43 PM
To: Clay, Nicholas <Nicholas.Clay@fda.hhs.gov>
Cc: K222743@docs.fda.gov
Subject: [EXTERNAL] Re: **(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.

Hi Nicholas,

(b)(4)

Please let me know if you have any additional questions.

Many thanks,

Kirsten

Route 92 Medical

650-279-8427

From: "Clay, Nicholas" <Nicholas.Clay@fda.hhs.gov<mailto:Nicholas.Clay@fda.hhs.gov>>
Date: Tuesday, September 13, 2022 at 7:14 AM
To: Kirsten Valley <kirsten@r92m.com<mailto:kirsten@r92m.com>>
Cc: "K222743@docs.fda.gov<mailto:K222743@docs.fda.gov>"
<K222743@docs.fda.gov<mailto:K222743@docs.fda.gov>>
Subject: **(b)(4)**

Good morning Kirsten:

My name is Nicholas Clay, and I am the lead reviewer for your recent 510(k) submission. As we continue our review, I was wondering if you could please clarify if

(b)(4)

Thank you again. Please let me know if you'd like to speak further.

Nicholas E. Clay, Ph.D.

Acting Team Lead

THT5A2: Neurointerventional Devices

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

10903 New Hampshire Avenue

Silver Spring, MD 20993

nicholas.clay@fda.hhs.gov<mailto:nicholas.clay@fda.hhs.gov>

[cid:image001.png@01D8C821.EDA63B80]<http://www.fda.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=1510&S=E<https://secure-web.cisco.com/1z-YPsQt7V18osB3zGP0Q7B5t-jUjb6X8XhKlxGJMQSMIHdRxpQQ6DMjtqoVHKqUKf0IiuW2mrPPmemFd_24Td9txji2nfcDr6xOvuep9Fp8mD9ceaBOZDhT-yuJ-cnWWMieg_K28_nlcStO7CUL2ylOJFwsXOmPpz_gLG2srjug7E_vGOupWpv6rZ_bkE5gdt4cAbUsthptAHybW4-1BHA/https%3A%2F%2Fwww.research.net%2F%2Fcdrhcustomerservice%3FID%3D1510%26S%3DE>

Declaration of Conformity with Design Controls

Ronie 92 Medical

As required by the risk analysis, all verification and validation activities were performed by designated individuals and results demonstrated that predetermined acceptance criteria were met.

The manufacturing facility is in conformance with design control procedure requirements as specified in 21 CFR 820.30 and the records are available for review.

(b)(6)

John Miller, Chief Technology Officer

9/8/22
Date

510(k) Summary K222743

(b)(4)

(b)(4)

(b)(4)

(b)(4)

INSTRUCTIONS FOR USE

(b)(4)

(b)(4)

INSTRUCTIONS FOR USE

(b)(4)

(b)(4)

Good morning Kirsten:

To help facilitate our review, could you please also address the following?

(b)(4)

If you could please respond to this request by noon tomorrow (9/15), then it will help facilitate our review.

Thank you again.

-Nick

From: Kirsten Valley <kirsten@r92m.com>
Sent: Tuesday, September 13, 2022 1:43 PM
To: Clay, Nicholas <Nicholas.Clay@fda.hhs.gov>
Cc: K222743@docs.fda.gov
Subject: [EXTERNAL] Re: (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.

Hi Nicholas,

You are correct. (b)(4)

Please let me know if you have any additional questions.

Many thanks,
Kirsten
Route 92 Medical
650-279-8427

From: "Clay, Nicholas" <Nicholas.Clay@fda.hhs.gov>
Date: Tuesday, September 13, 2022 at 7:14 AM
To: Kirsten Valley <kirsten@r92m.com>
Cc: "K222743@docs.fda.gov" <K222743@docs.fda.gov>
Subject: (b)(4)

Good morning Kirsten:

My name is Nicholas Clay, and I'm the lead reviewer for your recent 510(k) submission. As we continue our review, I was wondering if you could please clarify if (b)(4)

Thank you again. Please let me know if you'd like to speak further.

Nicholas E. Clay, Ph.D.
Acting Team Lead

TRTSA2: Neurointerventional Devices
DHTSA: Division of Neurosurgical, Neurointerventional and Neurodiagnostic Devices
OHTA: Office of Neurological and Physical Medicine Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health
16903 New Hampshire Avenue
Silver Spring, MD 20993

nicholas.clay@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=1510&S=E>



Food and Drug Administration
CDRH/OPEQ/OHTV/DHTVA
WO66 RM2524
10903 New Hampshire Ave
Silver Spring, MD 20993-0002

Premarket Notification 510(k) Review

Date: September 30, 2022			
Reviewer: Nicholas E. Clay, Ph.D.			
510(k)# K222743 Subject: Special			
Applicant: Route 92 Medical, Inc.		Device Trade Name: Route 92 Medical Full Length 070 Access System	
Contact Name: Kirsten Valley		Contact Title: Chief Operating Officer	
Correspondent Firm: Route 92 Medical, Inc.		Phone: (650) 279-8427 Email: kirsten@r92m.com	
Received Date: September 9, 2022		Due Date: October 9, 2022	
Pro Code(s): QJP Class: II Reg #: 870.1250		Reg Name: Percutaneous Catheter	
Predicate Devices:			
Submission #	Pro Code	Device Trade Name	Applicant
K210635	QJP	Route 92 Medical Full Length 088 Access System	Route 92 Medical Inc.
Recommendation			

(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)

(b)(5)

(b)(5)

510(k) Summary

(b)(4)

(b)(4)

(b)(4)

(b)(4)

Good afternoon Kirsten:

(b)(4)

Please let me know if you'd like to speak further. Thank you again.

Nicholas E. Clay, Ph.D.

Acting Team Lead

THT5A2: Neurointerventional Devices

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

10903 New Hampshire Avenue

Silver Spring, MD 20993

nicholas.clay@fda.hhs.gov<<mailto:nicholas.clay@fda.hhs.gov>>

[cid:image001.png@01D8D73D.0B054020]<<http://www.fda.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=1510&S=E>

Good morning Kirsten:

My name is Nicholas Clay, and I'm the lead reviewer for your recent 510(k) submission. As we continue our review, I was wondering if you could please clarify if
(b)(4)

Thank you again. Please let me know if you'd like to speak further.

Nicholas E. Clay, Ph.D.

Acting Team Lead

THSTA2: Neurointerventional Devices
DHTSA: Division of Neurosurgical, Neurointerventional and Neurodiagnostic Devices
OHTS: Office of Neurological and Physical Medicine Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health
10963 New Hampshire Avenue
Silver Spring, MD 20992

nicholas.clay@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=1510&S=E>

Indications for Use

510(k) Number (if known)

K222743

Device Name

Route 92 Medical Full Length 070 Access System

Indications for Use (Describe)

The Route 92 Medical Full Length 070 Access System is indicated for use with compatible guide catheters in facilitating the insertion and guidance of microcatheters into a selected blood vessel in the neurovascular system.

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."

Special 510(k) Notification, Route 92 Medical Full Length 070 Access System

**Section i: Medical Device User Fee Cover Sheet
(Form FDA 3601)**

Special 510(k) Notification, Route 92 Medical Full Length 070 Access System

8/9/22, 12:46 PM

Site: MDUFMA Cover Sheet

Form Approved OMB No. 0910-0511 Signature Date: October 31, 2004. See Instructions for OMB Approval

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) Route 92 Medical, Inc. 155 Bovet Road San Mateo California CA 94402 US	2. CONTACT NAME Kirsten Valley 2.1 E-MAIL ADDRESS kirsten@r92m.com 2.2 TELEPHONE NUMBER (include Area code) 408-230-1683 2.3 FACSIMILE (FAX) NUMBER (Include Area code)	1.1 EMPLOYER IDENTIFICATION NUMBER (EIN) *****1502
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> <input checked="" type="checkbox"/> Premarket notification(510(k)); except for third party <input type="checkbox"/> 513(g) Request for Information <input type="checkbox"/> Biologics License Application (BLA) <input type="checkbox"/> Premarket Approval Application (PMA) <input type="checkbox"/> Modular PMA <input type="checkbox"/> Product Development Protocol (PDP) <input type="checkbox"/> Premarket Report (PMR) <input type="checkbox"/> 30-Day Notice <input type="checkbox"/> De Novo Request		
3.1 Select a center <input checked="" type="checkbox"/> CDRH <input type="checkbox"/> CBER 3.2 Select one of the types below <input checked="" type="checkbox"/> Original Application <u>Supplement Types:</u> <input type="checkbox"/> Efficacy (BLA) <input type="checkbox"/> Panel Track (PMA, PMR, PDP) <input type="checkbox"/> Real-Time (PMA, PMR, PDP) <input type="checkbox"/> 180-day (PMA, PMR, PDP)		
4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status) <input checked="" type="checkbox"/> YES, I meet the small business criteria and have submitted the required qualifying documents to FDA <input type="checkbox"/> NO, I am not a small business 4.1 If Yes, please enter your Small Business Decision Number: (b)(4)		
5. FDA WILL NOT ACCEPT YOUR SUBMISSION IF YOUR COMPANY HAS NOT PAID AN ESTABLISHMENT REGISTRATION FEE THAT IS DUE TO FDA. HAS YOUR COMPANY PAID ALL ESTABLISHMENT REGISTRATION FEES THAT ARE DUE TO FDA? <input checked="" type="checkbox"/> YES (All of 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.) <input type="checkbox"/> 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. <input type="checkbox"/> This application is the first PMA submitted by a qualified small business, including any affiliates <input type="checkbox"/> This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only <input type="checkbox"/> The sole purpose of the application is to support conditions of use for a pediatric population <input type="checkbox"/> The application is submitted by a state or federal government entity for a device that is not to be distributed commercially		
7. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION OF USE FOR ANY ADULT POPULATION? (If so, the application is subject to the fee that applies for an original premarket approval application (PMA).) <input type="checkbox"/> YES <input checked="" type="checkbox"/> NO		
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,		

[https://userfees.fda.gov/CA_HTML/mdufma/CSofCfItemsPopUp.jsp?ordnum=: \(b\)\(4\)](https://userfees.fda.gov/CA_HTML/mdufma/CSofCfItemsPopUp.jsp?ordnum=: (b)(4))

1/2

Special 510(k) Notification, Route 92 Medical Full Length 070 Access System

8/9/22, 12:46 PM

Site: MDUFMA Cover Sheet

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
Paperwork 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.]

B. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION

(b)(4)

09-Aug-2022

Form FDA 5081 (09/03)

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

[https://userfees.fda.gov/OA_HTML/mdufma/SecCtgItemsPopUp.jsp?ordnum=\(b\)\(4\)](https://userfees.fda.gov/OA_HTML/mdufma/SecCtgItemsPopUp.jsp?ordnum=(b)(4))

2/2

510(k) Summary

(b)(4)

(b)(4)

(b)(4)

(b)(4)

Table 5-1: Summary of Design Control Activities

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

Thank you for your rapid reply, Kirsten. If we have any other questions, I'll let you know.

From: Kirsten Valley <kirsten@r92m.com>
Sent: Tuesday, September 13, 2022 1:43 PM
To: Clay, Nicholas <Nicholas.Clay@fda.hhs.gov>
Cc: K222743@docs.fda.gov
Subject: [EXTERNAL] Re: (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.

Hi Nicholas,

(b)(4)

Please let me know if you have any additional questions.

Many thanks,
Kirsten
Route 92 Medical
650-279-8427

From: "Clay, Nicholas" <Nicholas.Clay@fda.hhs.gov<mailto:Nicholas.Clay@fda.hhs.gov>>
Date: Tuesday, September 13, 2022 at 7:14 AM
To: Kirsten Valley <kirsten@r92m.com<mailto:kirsten@r92m.com>>
Cc: "K222743@docs.fda.gov<mailto:K222743@docs.fda.gov>"
<K222743@docs.fda.gov<mailto:K222743@docs.fda.gov>>
Subject: (b)(4)

Good morning Kirsten:

My name is Nicholas Clay, and I'm the lead reviewer for your recent 510(k) submission. As we continue our review, I was wondering if you could please clarify if

(b)(4)

Thank you again. Please let me know if you'd like to speak further.

Nicholas E. Clay, Ph.D.
Acting Team Lead

THT5A2: Neurointerventional Devices
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
10903 New Hampshire Avenue

Silver Spring, MD 20993

nicholas.clay@fda.hhs.gov<mailto:nicholas.clay@fda.hhs.gov>

[cid:image001.png@01D8C7B3.77D8CD00]<http://www.fda.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=1510&S=E<https://secure-web.cisco.com/1z-YPsQt7V18osB3zGP0Q7B5t-jUjb6X8XhKlxGJMqSMIHdRxpQQ6DMjtqoVHKqUKf0IiuW2mrPPmemFd_24Td9txji2nfcDr6xOvuep9Fp8mD9ceaBOZDhT-yuJ-cnWWMieg_K28_nlcSt07CUL2yl0JFwsXOmPpz_gLG2srjug7E_vGoupWpv6rZ_bkE5gdt4cAbUsthptAHybW4-1BHA/https%3A%2F%2Fwww.research.net%2Fs%2Fcdrhcustomerservice%3FID%3D1510%26S%3DE>

Indications for Use

(b)(4)

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

(b)(4)

(b)(4)

(b)(4)

(b)(4)



October 4, 2022

Route 92 Medical
Kirsten Valley
Chief Operating Officer
155 Bovet Road, Suite 100
San Mateo, California 94402

Re: K222743

Trade/Device Name: Route 92 Medical Full Length 070 Access System
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: QJP
Dated: September 8, 2022
Received: September 9, 2022

Dear Kirsten Valley:

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

Hi Nick,

Attached please find our responses to your questions. Also attached is an updated (b)(4)

Please let me know if you have any additional questions.

Many thanks,
Kirsten

Route 92 Medical
650-279-8427

From: "Clay, Nicholas" <Nicholas.Clay@fda.hhs.gov>
Date: Tuesday, September 27, 2022 at 4:19 PM
To: Kirsten Valley <kirsten@r92m.com>
Cc: "K222743@docs.fda.gov" <K222743@docs.fda.gov>
Subject: RE: [EXTERNAL] Re: Additional Questions Regarding K222743

Thank you for your response, Kirsten. I was hoping you could please address the following as well:

(b)(4)

If you could please respond by noon Eastern on Wednesday (09/28), then it will help facilitate our review. If possible, please kindly confirm acceptance of this email at your earliest convenience.

Thank you again.

-Nick

From: Kirsten Valley <kirsten@r92m.com>
Sent: Sunday, September 25, 2022 10:55 AM
To: Clay, Nicholas <Nicholas.Clay@fda.hhs.gov>
Cc: K222743@docs.fda.gov
Subject: [EXTERNAL] Re: Additional Questions Regarding K222743

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.

Hello Nick,

Attached, please find the responses to your questions. Please let me know if you have any additional questions.

Many thanks,
Kirsten

Route 92 Medical
650-279-8427

From: "Clay, Nicholas" <Nicholas.Clay@fda.hhs.gov>
Date: Thursday, September 22, 2022 at 9:19 PM
To: Kirsten Valley <kirsten@r92m.com>
Cc: "K222743@docs.fda.gov" <K222743@docs.fda.gov>
Subject: Additional Questions Regarding K222743

Good afternoon Kirsten:

As we continue our review of K222743, I was wondering if you could please answer the following questions:

(b)(4)

(b)(4)

If you could please respond to this request by **9 am (Eastern) on 09/26**, then it will help facilitate our review.

Please let me know if you want to discuss further. Thank you again.

Nicholas E. Clay, Ph.D.

Acting Team Lead

THSA2: Neurointerventional Devices
DHTSA: Division of Neurosurgical, Neurointerventional and Neurodiagnostic Devices
OHTS: Office of Neurological and Physical Medicine Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health
16903 New Hampshire Avenue
Silver Spring, MD 20993

nicholas.clay@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=1510&S=E>

Good Morning Nick,

Attached are redlined and clean (b)(4) Apologies for the error.

(b)(4)

Lastly, there have been no prior submissions for this device.

Please let me know if you have any additional questions.

Many thanks,
Kirsten

From: "Clay, Nicholas" <Nicholas.Clay@fda.hhs.gov>
Date: Wednesday, September 14, 2022 at 7:22 AM
To: Kirsten Valley <kirsten@r92m.com>
Cc: "K222743@docs.fda.gov" <K222743@docs.fda.gov>
Subject: RE: [EXTERNAL] Re: (b)(4)

Good morning Kirsten:

To help facilitate our review, could you please also address the following?

(b)(4)

If you could please respond to this request by noon tomorrow (9/15), then it will help facilitate our review.

Thank you again.

-Nick

From: Kirsten Valley <kirsten@r92m.com>
Sent: Tuesday, September 13, 2022 1:43 PM
To: Clay, Nicholas <Nicholas.Clay@fda.hhs.gov>
Cc: K222743@docs.fda.gov
Subject: [EXTERNAL] Re: (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.

Hi Nicholas,

(b)(4)

Please let me know if you have any additional questions.

Many thanks,
Kirsten
Route 92 Medical
650-279-8427

From: "Clay, Nicholas" <Nicholas.Clay@fda.hhs.gov>
Date: Tuesday, September 13, 2022 at 7:14 AM
To: Kirsten Valley <kirsten@r92m.com>
Cc: "K222743@docs.fda.gov" <K222743@docs.fda.gov>
Subject: (b)(4)

Good morning Kirsten:

My name is Nicholas Clay, and I'm the lead reviewer for your recent 510(k) submission. As we continue our review, I was wondering if you could please clarify if (b)(4)

Thank you again. Please let me know if you'd like to speak further.

Nicholas E. Clay, Ph.D.
Acting Team Lead

THESA2: Neurointerventional Devices
DHTSA: Division of Neurosurgical, Neurointerventional and Neurodiagnostic Devices
OHTS: Office of Neurological and Physical Medicine Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health
10883 New Hampshire Avenue
Silver Spring, MD 20993

nicholas.clay@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=1510&S=E>

Thank you for providing clarification, Kirsten.

From: Kirsten Valley <kirsten@r92m.com>
Sent: Thursday, September 15, 2022 10:10 AM
To: Clay, Nicholas <Nicholas.Clay@fda.hhs.gov>
Cc: K222743@docs.fda.gov
Subject: Re: [EXTERNAL] Re: (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 Nick,

Attached are redlined and (b)(4)
(b)(4) Apologies for the error.

(b)(4)

Lastly, there have been no prior submissions for this device.

Please let me know if you have any additional questions.

Many thanks,

Kirsten

From: "Clay, Nicholas" <Nicholas.Clay@fda.hhs.gov<mailto:Nicholas.Clay@fda.hhs.gov>>
Date: Wednesday, September 14, 2022 at 7:22 AM
To: Kirsten Valley <kirsten@r92m.com<mailto:kirsten@r92m.com>>
Cc: "K222743@docs.fda.gov<mailto:K222743@docs.fda.gov>"
<K222743@docs.fda.gov<mailto:K222743@docs.fda.gov>>
Subject: RE: [EXTERNAL] Re: (b)(4)

Good morning Kirsten:

To help facilitate our review, could you please also address the following?

(b)(4)

If you could please respond to this request by noon tomorrow (9/15), then it will help facilitate our review.

Thank you again.

-Nick

From: Kirsten Valley <kirsten@r92m.com<mailto:kirsten@r92m.com>>
Sent: Tuesday, September 13, 2022 1:43 PM
To: Clay, Nicholas <Nicholas.Clay@fda.hhs.gov<mailto:Nicholas.Clay@fda.hhs.gov>>
Cc: K222743@docs.fda.gov<mailto:K222743@docs.fda.gov>
Subject: [EXTERNAL] Re: (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.

Hi Nicholas,

(b)(4)

Please let me know if you have any additional questions.

Many thanks,

Kirsten

Route 92 Medical

650-279-8427

From: "Clay, Nicholas" <Nicholas.Clay@fda.hhs.gov<mailto:Nicholas.Clay@fda.hhs.gov>>
Date: Tuesday, September 13, 2022 at 7:14 AM
To: Kirsten Valley <kirsten@r92m.com<mailto:kirsten@r92m.com>>
Cc: "K222743@docs.fda.gov<mailto:K222743@docs.fda.gov>"
<K222743@docs.fda.gov<mailto:K222743@docs.fda.gov>>
Subject: (b)(4)

Good morning Kirsten:

My name is Nicholas Clay, and I am the lead reviewer for your recent 510(k) submission. As we continue our review, I was wondering if you could please clarify if

(b)(4)

Thank you again. Please let me know if you would like to speak further.

Nicholas E. Clay, Ph.D.

Acting Team Lead

THT5A2: Neurointerventional Devices

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

10903 New Hampshire Avenue

Silver Spring, MD 20993

nicholas.clay@fda.hhs.gov<mailto:nicholas.clay@fda.hhs.gov>

[cid:image001.png@01D8C8F0.7BC78850]<http://www.fda.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=1510&S=E<https://secure-web.cisco.com/1z-YPsQt7V18osB3zGP0Q7B5t-jUjb6X8XhKlxGJMqSMIHdRxpQQ6DMjtqoVHKqUKf0IiuW2mrPPmemFd_24Td9txji2nfcDr6xOvuep9Fp8mD9ceaBOZDhT-yuJ-cnWWMieg_K28_nlcSt07CUL2yl0JFwsXOmPpz_gLG2srjug7E_vGoupWpv6rZ_bkE5gdt4cAbUsthptAHybW4-1BHA/https%3A%2F%2Fwww.research.net%2Fs%2Fcdrhcustomerservice%3FID%3D1510%26S%3DE>

Thank you for your response, Kirsten. I was hoping you could please address the following as well:

(b)(4)

If you could please respond by noon Eastern on Wednesday (09/28), then it will help facilitate our review. If possible, please kindly confirm acceptance of this email at your earliest convenience.

Thank you again.

-Nick

From: Kirsten Valley <kirsten@r92m.com>
Sent: Sunday, September 25, 2022 10:55 AM
To: Clay, Nicholas <Nicholas.Clay@fda.hhs.gov>
Cc: K222743@docs.fda.gov
Subject: [EXTERNAL] Re: Additional Questions Regarding K222743

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.

Hello Nick,

Attached, please find the responses to your questions. Please let me know if you have any additional questions.

Many thanks,
Kirsten

Route 92 Medical
650-279-8427

From: "Clay, Nicholas" <Nicholas.Clay@fda.hhs.gov>
Date: Thursday, September 22, 2022 at 9:19 PM
To: Kirsten Valley <kirsten@r92m.com>
Cc: "K222743@docs.fda.gov" <K222743@docs.fda.gov>
Subject: Additional Questions Regarding K222743

Good afternoon Kirsten:

As we continue our review of K222743, I was wondering if you could please answer the following questions:

(b)(4)

If you could please respond to this request by **9 am (Eastern) on 09/26**, then it will help facilitate our review.

Please let me know if you want to discuss further. Thank you again.

Nicholas E. Clay, Ph.D.
Acting Team Lead

TH TSA2: Neurointerventional Devices
DHTSA: Division of Neurosurgical, Neurointerventional and Neurodiagnostic Devices
OHTS: Office of Neurological and Physical Medicine Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health
16000 New Hampshire Avenue
Silver Spring, MD 20993

nicholas.clay@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=1510&S=E>

Hi Nick,

The requested edits to the (b)(4) Please let me know if you need any additional information.

Many thanks,
Kirsten

Route 92 Medical
650-279-8427

From: "Clay, Nicholas" <Nicholas.Clay@fda.hhs.gov>
Date: Monday, October 3, 2022 at 12:30 PM
To: Kirsten Valley <kirsten@r92m.com>
Cc: "K222743@docs.fda.gov" <K222743@docs.fda.gov>
Subject: Time-Sensitive: Requested Edits to (b)(4) (Please Confirm Receipt)

Good afternoon Kirsten:

Thank you for previously participating in IR for this submission. Could you please make the requested edits (attached) to the (b)(4) by COB 10/04?

Please let me know if you'd like to speak further. Thank you again.

Nicholas E. Clay, Ph.D.
Acting Team Lead

THSA2: Neurointerventional Devices
DHTSA: Division of Neurosurgical, Neurointerventional and Neurodiagnostic Devices
OHTS: Office of Neurological and Physical Medicine Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health
16903 New Hampshire Avenue
Silver Spring, MD 20993

nicholas.clay@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://secure-web.cisco.com/1ldobmukHryHu5G86dF9F2lUvmg5vUXHWYCO8N7NbZnCMVe1uv9liZWof0svdTrXfgfBUeZZoFbW5cm9UrGbjN3F-FrPSncWZB5FqIATvrXzhuHm5LwoONkoRmbCHmZ4rI27QS2udaDYoBOTO7V325h2PZiub8qLAP2vAGL5sE-Lh8wmZGyt4mMkjhex3-zgM/https%3A%2F%2Fwww.research.net%2Fs%2Fcdhcustomerservice%3FID%3D1510%26S%3DE>

Hi Nick,

The requested edits to the (b)(4).
Please let me know if you need any additional information.

Many thanks,

Kirsten

Route 92 Medical

650-279-8427

From: "Clay, Nicholas" <Nicholas.Clay@fda.hhs.gov>

Date: Monday, October 3, 2022 at 12:30 PM

To: Kirsten Valley <kirsten@r92m.com>

Cc: "K222743@docs.fda.gov" <K222743@docs.fda.gov>

Subject: Time-Sensitive: Requested Edits to (b)(4) (Please Confirm Receipt)

Good afternoon Kirsten:

Thank you for previously participating in IR for this submission. Could you please make the requested edits (attached) to the (b)(4) by COB 10/04?

Please let me know if you'd like to speak further. Thank you again.

Nicholas E. Clay, Ph.D.

Acting Team Lead

THT5A2: Neurointerventional Devices

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

10903 New Hampshire Avenue

Silver Spring, MD 20993

nicholas.clay@fda.hhs.gov<mailto:nicholas.clay@fda.hhs.gov>

[cid:image001.png@01D8D743.41836360]<http://www.fda.gov/>

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

https://secure-web.cisco.com/1IdobmukHryHu5G86dF9F2IJVmg5vUXHWYCO8N7NbZnCMVe1uv9IjZWof0svdTrXfgfBUeZZoFbW5cm9UrGbjN3F_FrPSncWZB5Fq1ATvrXzhuHm5Lwo0NkoRmbCHmZ4rI27QS2udaDYoB0TO7V325h2PZiub8qLAP2vAGL5sE-Lh8wmZGYt4mMkjhex3-zgM/https%3A%2F%2Fwww.research.net%2Fs%2Fcdrhcustomerservice%3FID%3D1510%26S%3DE

Thank you for your response, Kirsten.

From: Kirsten Valley <kirsten@r92m.com>

Sent: Wednesday, September 28, 2022 11:19 AM

To: Clay, Nicholas <Nicholas.Clay@fda.hhs.gov>

Cc: K222743@docs.fda.gov

Subject: Re: [EXTERNAL] Re: Additional Questions Regarding K222743

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.

Hi Nick,

Attached please find our responses to your questions. Also attached is an updated

(b)(4)

Please let me know if you have any additional questions.

Many thanks,

Kirsten

Route 92 Medical

650-279-8427

From: "Clay, Nicholas" <Nicholas.Clay@fda.hhs.gov<mailto:Nicholas.Clay@fda.hhs.gov>>

Date: Tuesday, September 27, 2022 at 4:19 PM

To: Kirsten Valley <kirsten@r92m.com<mailto:kirsten@r92m.com>>

Cc: "K222743@docs.fda.gov<mailto:K222743@docs.fda.gov>"
<K222743@docs.fda.gov<mailto:K222743@docs.fda.gov>>

Subject: RE: [EXTERNAL] Re: Additional Questions Regarding K222743

Thank you for your response, Kirsten. I was hoping you could please address the following as well:

(b)(4)

If you could please respond by noon Eastern on Wednesday (09/28), then it will help facilitate our review. If possible, please kindly confirm acceptance of this email at your earliest convenience.

Thank you again.

-Nick

From: Kirsten Valley <kirsten@r92m.com<mailto:kirsten@r92m.com>>
Sent: Sunday, September 25, 2022 10:55 AM
To: Clay, Nicholas <Nicholas.Clay@fda.hhs.gov<mailto:Nicholas.Clay@fda.hhs.gov>>
Cc: K222743@docs.fda.gov<mailto:K222743@docs.fda.gov>
Subject: [EXTERNAL] Re: Additional Questions Regarding K222743

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.

Hello Nick,

Attached, please find the responses to your questions. Please let me know if you have any additional questions.

Many thanks,

Kirsten

Route 92 Medical
650-279-8427

From: "Clay, Nicholas" <Nicholas.Clay@fda.hhs.gov<mailto:Nicholas.Clay@fda.hhs.gov>>
Date: Thursday, September 22, 2022 at 9:19 PM
To: Kirsten Valley <kirsten@r92m.com<mailto:kirsten@r92m.com>>
Cc: "K222743@docs.fda.gov<mailto:K222743@docs.fda.gov>"
<K222743@docs.fda.gov<mailto:K222743@docs.fda.gov>>
Subject: Additional Questions Regarding K222743

Good afternoon Kirsten:

As we continue our review of K222743, I was wondering if you could please answer the following questions:

(b)(4)

If you could please respond to this request by 9 am (Eastern) on 09/26, then it will help facilitate our review.

Please let me know if you want to discuss further. Thank you again.

Nicholas E. Clay, Ph.D.

Acting Team Lead

THT5A2: Neurointerventional Devices

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

10903 New Hampshire Avenue

Silver Spring, MD 20993

nicholas.clay@fda.hhs.gov<mailto:nicholas.clay@fda.hhs.gov>

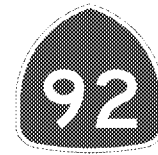
[cid:image001.png@01D8D347.172614A0]<<http://www.fda.gov/>>

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=1510&S=E<https://secure-web.cisco.com/1pafvORR1D20HswXAk5ZXSD6-7OcBYIpEFUcYXmH2BSn4h-k7De0RYKHmLz6i_11FiilU9a4LIan-83edBKZYeOiBGa-_GJ2083e7-zAlfjJK-VJgo6AziVbJ5mrhs8AGnvEB_o0RmHKMbHsClWdvgcF90Bb3naiiTt6KpW1zKgJ20xUwbXBpkaFrjrqrAzOrFWjY-dQFGarIRuOX5QJvch4NVNAkkDx_24e5YqIhbU/https%3A%2F%2Fwww.research.net%2Fs%2Fcdrhcustomer-service%3FID%3D1510%26S%3DE>

ROUTE 92 MEDICAL

155 Bovet Road, Suite 100
SAN MATEO, CA 94402
E-Mail: INFO@R92M.COM
Web: R92M.COM



September 8, 2022
Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

K222743

FDA/CDRH/DCC

SEP 09 2022

RECEIVED

Regulation Number: 21 CFR 870.1250
Regulation Name: Neurovascular Percutaneous Catheter
Regulation Class: Class II
Panel: Neurology
Product Code: QJP

Re: Special 510(k) for Route 92 Medical Full Length 070 Access System, Device Modification to K210635 (Route 92 Medical Full Length 088 Access System)

Dear 510(k) Review Team:

Route 92 Medical is submitting the enclosed **Special 510(k)** notification to request clearance for a change to the Route 92 Medical Full Length 088 Access System cleared under K210635. The modified device, the Route 92 Medical Full Length 070 Access System, is being manufactured and submitted by the manufacturer authorized to market the existing, unmodified device.

The Indications for Use of the modified device are unchanged from the predicate, legally marketed device. Like the previously cleared Route 92 Medical Full Length 088 Access System (K210635), the modified device, the Route 92 Medical Full Length 070 Access System, is indicated for use with compatible guide catheters in facilitating the insertion and guidance of microcatheters into a selected blood vessel in the neurovascular system, and is provided for single use and by prescription use only. In addition, the fundamental scientific technology of the modified device is unchanged from the legally marketed device. Well-established methods have been used to evaluate the change and summary-level performance data conducted under design validation (21 CFR 820.30(g)) have been submitted in accordance with the Special 510(k) provisions. There have been no prior submissions for this device.

Route 92 Medical considers our intent to market this device as confidential commercial information and requests that it be treated as such by FDA per 21 CFR 807.95. The company has taken reasonable precautions to protect this confidentiality.

Thank you in advance for your consideration of this application. Please direct any questions or requests for additional information to me at the below phone number or by electronic mail.

Sincerely,

(b)(6)

Kirsten Valley
Chief Operating Officer
Route 92 Medical, Inc.
Phone: (650)-279-8427
Email: kirsten@r92m.com

Included: one (1) eCopy of Special 510(k)