



August 12, 2025

Medical Components, Inc.
Danielle Mckinney
Senior Regulatory Affairs Specialist
1499 Delp Drive
Harleysville, PA 19438

Re: K250836
Trade/Device Name: 14F Duo-Flow® Side X Side Double Lumen Catheter
Regulation Number: 21 CFR§ 876.5540
Regulation Name: Blood Access Device and Accessories
Regulatory Class: II
Product Code: MPB
Dated: July 21, 2025
Received: July 21, 2025

Dear Danielle Mckinney:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (<https://www.fda.gov/media/99812/download>) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (<https://www.fda.gov/media/99785/download>).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system>.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Maura Rooney -S

Maura Rooney

Assistant Director

DHT3A: Division of Renal, Gastrointestinal,
Obesity, and Transplant Devices

OHT3: Office of Gastrorenal, ObGyn,
General Hospital, and Urology Devices

Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Submission Number (if known)

K250836

Device Name

14F Duo-Flow® Side X Side Double Lumen Catheter

Indications for Use (Describe)

The Duo-Flow® Side X Side double lumen catheter is intended for short-term central venous access for hemodialysis, apheresis and infusion.

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.

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

Traditional 510(k): 510(k) Summary

Submitter Information:

510(k) Submitted By: Medical Components, Inc. (dba MedComp)
1499 Delp Drive
Harleysville, PA 19438
United States of America

Primary Correspondent: Danielle McKinney, Senior Regulatory Affairs Specialist
regulatory@medcompnet.com
843-467-5661

Date Prepared: February 25, 2025

Subject Device Information:

Trade Name: 14F Duo-Flow® Side x Side Double Lumen Catheter

Common Name: Short-Term Hemodialysis Catheter

Classification Regulation: Blood access device and accessories,
21 CFR 876.5540

Device Class: Class II

Classification Panel: Gastroenterology/Urology

Product Code: MPB

Predicate Device Information:

Trade Name (predicate): Duo-Flow® Side x Side Double Lumen Catheter

Common Name (predicate): Short-Term Hemodialysis Catheter

Classification Regulation: Blood access device and accessories,
21 CFR 876.5540

Device Class: Class II

Classification Panel: Gastroenterology/Urology

Product Code: MPB

Predicate 510(k) Number: K192807

Predicate 510(k) Owner: Medical Components, Inc. (dba MedComp)



Device Description:

The Duo-Flow® Side X Side double lumen catheter is a radiopaque, polyurethane tube with two D-shaped lumina. The lumina can be distinguished by the color-coded luer:

- Red Adaptor = proximal lumen
- Blue Adaptor = distal lumen

The proximal lumen provides "arterial" outflow from the patient; the distal lumen provides "venous" return.

The catheter comes in a variety of sizes and is offered with curved or straight extensions.

Intended Use:

The Duo-Flow® Side X Side double lumen catheter is intended for short-term central venous access for hemodialysis, apheresis and infusion.

Summary of Technological Characteristics:

The subject device has similar technological characteristics as the predicate device. The Duo-Flow® Side x Side Catheter removes and returns blood through two segregated lumen passages. Each lumen is connected to an extension line with color-coded female luer connectors. The transition between lumen and extension is housed within a molded hub. Both arterial and venous lumens contain side-holes. The catheter incorporates Barium Sulphate to facilitate visualization under fluoroscopy or Xray. All sizes of the Duo-Flow® Side x Side Catheter are available in a Basic Set intended to be used in an Interventional Radiology or Operating Suite. The Set includes primary insertion componentry for the Modified Seldinger Insertion Technique. Based on the similarity of these technological characteristics, there are no changes that affect the safety or effectiveness of the 14F Duo-Flow Side x Side Double Lumen Catheter.

Substantial Equivalence Discussion:

The Substantial Equivalence Comparison Table below provides evidence to facilitate the substantial equivalence determination between the 14F Duo-Flow® Side x Side Double Lumen Catheter to the predicate device Duo-Flow® Side x Side Double Lumen Catheter.

Table 1 - Substantial Equivalence		
Description	Subject Device	Predicate Device
Device Trade Name	14F Duo-Flow® Side x Side Double Lumen Catheter	Duo-Flow® Side x Side Double Lumen Catheter
510(k) submitter/holder	Medical Components Inc. (dba MedComp)	Medical Components Inc. (dba MedComp)
510(k) Number	K250836	K192807, cleared on April 23, 2020
Intended Use	The Duo-Flow® Side X Side double lumen catheter is intended for short-term central venous access for hemodialysis, apheresis and infusion.	The Duo-Flow® Side X Side double lumen catheter is intended for short-term central venous access for hemodialysis, apheresis and infusion.
Prescription/Over-the-Counter Use	Prescription	Prescription
Target Population	Adult	Adult
Duration of Use	Short-Term	Short-Term
Sterilization Method	1x and/or 2x EO Sterilized	1x and/or 2x EO Sterilized



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Inner Diameters (in)	14F - .140±.003	9F - .097" ±.002 11F - .114" ±.003 12F - .114" ±.003																																																																																																															
Outer Diameters (in)	14F - .190±.003	9F - .125" ±.002 11F - .160" ±.003 12F - .160" ±.003																																																																																																															
Number of Lumens	Two (2)	Two (2)																																																																																																															
Catheter Lengths	14F Straight - 15cm, 20cm, 24cm 14F Curved - 15cm, 20cm, 24cm	9F Straight – 10cm, 12cm, 15cm, 20cm 9F Curved – 7.5cm, 12cm, 15cm 11F Straight – 12cm, 15cm, 20cm, 24cm 11F Curved – 10cm, 12cm, 15cm, 20cm 12F Straight - 15cm, 20cm, 24cm 12F Curved – 13cm, 15cm, 20cm																																																																																																															
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rowspan="2">10cm</td><td>V</td><td>40</td><td>92</td><td>109</td><td>N/A</td><td>147</td></tr><tr><td>A</td><td>-34</td><td>-63</td><td>-99</td><td>N/A</td><td>-139</td></tr><tr><td rowspan="2">12cm</td><td>V</td><td>47</td><td>83</td><td>124</td><td>144</td><td>166</td></tr><tr><td>A</td><td>-41</td><td>-72</td><td>-110</td><td>-129</td><td>-148</td></tr><tr><td rowspan="2">15cm</td><td>V</td><td>52</td><td>88</td><td>131</td><td>150</td><td>173</td></tr><tr><td>A</td><td>-48</td><td>-80</td><td>-119</td><td>-139</td><td>-160</td></tr><tr><td rowspan="2">20cm</td><td>V</td><td>60</td><td>104</td><td>154</td><td>177</td><td>N/A</td></tr><tr><td>A</td><td>-59</td><td>-96</td><td>-141</td><td>-162</td><td>N/A</td></tr><tr><td colspan="6">9F Curved</td></tr><tr><td rowspan="2">7.5cm</td><td>V</td><td>46</td><td>75</td><td>113</td><td>N/A</td><td>154</td></tr><tr><td>A</td><td>-33</td><td>-53</td><td>-86</td><td>N/A</td><td>-123</td></tr><tr><td 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rowspan="2">24cm</td><td>V</td><td>39</td><td>71</td><td>116</td><td>N/A</td><td>167</td></tr><tr><td>A</td><td>-40</td><td>-63</td><td>-101</td><td>N/A</td><td>-141</td></tr><tr><td colspan="6">11F Curved</td></tr><tr><td rowspan="2">10cm</td><td>V</td><td>30</td><td>54</td><td>85</td><td>N/A</td><td>120</td></tr><tr><td>A</td><td>-21</td><td>-42</td><td>-69</td><td>N/A</td><td>-95</td></tr><tr><td rowspan="2">12cm</td><td>V</td><td>30</td><td>54</td><td>85</td><td>N/A</td><td>120</td></tr><tr><td>A</td><td>-21</td><td>-42</td><td>-69</td><td>N/A</td><td>-95</td></tr><tr><td rowspan="2">15cm</td><td>V</td><td>41</td><td>68</td><td>101</td><td>N/A</td><td>112</td></tr><tr><td>A</td><td>-20</td><td>-42</td><td>-70</td><td>N/A</td><td>-101</td></tr><tr><td rowspan="2">20cm</td><td>V</td><td>44</td><td>72</td><td>105</td><td>124</td><td>141</td></tr><tr><td>A</td><td>-29</td><td>-49</td><td>-76</td><td>-91</td><td>-108</td></tr><tr><td colspan="6">12F Straight</td></tr><tr><td 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rowspan="2">20cm</td><td>V</td><td>40</td><td>69</td><td>107</td><td>N/A</td><td>153</td></tr><tr><td>A</td><td>-31</td><td>-59</td><td>-90</td><td>N/A</td><td>-126</td></tr></table>						Flow Rate (ml/min)	200	300	400	450	500	9F Straight						10cm	V	40	92	109	N/A	147	A	-34	-63	-99	N/A	-139	12cm	V	47	83	124	144	166	A	-41	-72	-110	-129	-148	15cm	V	52	88	131	150	173	A	-48	-80	-119	-139	-160	20cm	V	60	104	154	177	N/A	A	-59	-96	-141	-162	N/A	9F Curved						7.5cm	V	46	75	113	N/A	154	A	-33	-53	-86	N/A	-123	12cm	V	49	89	131	153	171	A	-52	-87	-134	-158	-180	15cm	V	61	103	158	175	199	A	-43	-81	-129	-152	-176	11F Straight						12cm	V	31	59	91	N/A	129	A	-30	-50	-80	N/A	-110	15cm	V	28	54	83	N/A	119	A	-32	-52	-78	N/A	-108	20cm	V	44	72	105	124	141	A	-29	-49	-76	-91	-108	24cm	V	39	71	116	N/A	167	A	-40	-63	-101	N/A	-141	11F Curved						10cm	V	30	54	85	N/A	120	A	-21	-42	-69	N/A	-95	12cm	V	30	54	85	N/A	120	A	-21	-42	-69	N/A	-95	15cm	V	41	68	101	N/A	112	A	-20	-42	-70	N/A	-101	20cm	V	44	72	105	124	141	A	-29	-49	-76	-91	-108	12F Straight						15cm	V	30	57	90	N/A	130	A	-27	-49	-74	N/A	-106	20cm	V	32	62	101	N/A	150	A	-30	-55	-89	N/A	-122	24cm	V	40	70	114	N/A	166	A	-37	-62	-99	N/A	-137	12F Curved						13cm	V	32	60	96	N/A	138	A	-31	-52	-81	N/A	-113	15cm	V	40	68	101	N/A	141	A	-22	-43	-70	N/A	-101	20cm	V	40	69	107	N/A	153	A	-31	-59	-90	N/A	-126
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Summary of Non-Clinical Testing:

Biocompatibility:

A biocompatibility evaluation was performed in accordance with the FDA Guidance 'Use of International Standard ISO 10993-1, "Biological evaluation of medical devices – Part 1:'



Evaluation and testing within a risk management process”. Biocompatibility testing was leveraged from the predicate device manufactured by Medical Components, Inc. Clinical testing was not required nor performed to support the substantial equivalence of these devices.

Performance Testing:

Design Verification and Validation performance testing was performed in accordance with Design Controls as per 21 CFR 820.30. Bench testing was performed to evaluate the performance of the subject device on:

- Dimensional Analysis
- Air Leakage
- Liquid Leakage
- % Lumen Elongation
- ISO 80369-7 Stress Cracking
- ISO 80369-7 Luer Testing
- Kink Resistance
- Gravity Flow Rate
- Flow vs Pressure
- Priming Volume
- Clamp Cycle
- Simulated Use
- Electrical Conductivity
- Force at Break
- Packaging Validation

Clinical testing was not required nor performed to support the substantial equivalence of these devices.

Conclusion

In conclusion, based on the non-clinical testing performed, the subject device 14F Duo-Flow® Side x Side Double Lumen Catheter is substantially equivalent to the predicate device Duo-Flow® Side x Side Double Lumen Catheter (K192807) and does not raise any concern for the safety and effectiveness of the subject device.