K961445

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SECTION II Summary and Certification

SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION PERTAINING TO SUBSTANTIAL EQUIVALENCE

Proprietary Device Name: RADIFOCUS® Glidewire® for coronary use with platinum (or gold) coil*
*These wires may also be called by a proprietary name of just CROSSWIRE®.

Classification Name: Wire, Guide, Catheter

INTENDED USE

The RADIFOCUS Glidewires for coronary use with platinum (or gold) coil are used to facilitate the placement of ballon dilatation catheters for percutaneous transluminal coronary angioplasty (PTCA) and/or percutaneous transluminal angioplasty (PTA).

Note: This is the same intended use as the Terumo Coronary Guide Wires cleared under 510(k) K953533.

DESCRIPTION

The RADIFOCUS Glidewires for coronary use with platinum (or gold) coil have a core of titanium nickel alloy coated with polyurethane which is second coated with a hydrogel. The wires are 180cm and 300cm in length and come in 0.014", 0.016" and 0.018" diameters respectively. The platinum coil wire, 300cm length, is used exclusively for exchange purposes. The wires also possess a radiopaque marker at the tip of the wire. This coil is made of an amalgam of platinum and iridium or gold. The coil is entirely coated with polyurethane with tungsten. The distal portion of the wire is gradually tapered from 10 to 30 cm in length providing increasing flexibility at the distal portion of the wire.

SUBSTANTIAL EQUIVALENCE

The Terumo RADIFOCUS® Glidewires® for coronary use with platinum (or gold) coil submitted in this 510(k) are substantially equivalent in intended use, design, technology/principles of operation, materials and performance to the cleared Terumo RADIFOCUS Glidewires for coronary use with platinum (or gold) coil K953533.

PRINCIPLE OF OPERATION/TECHNOLOGY

The RADIFOCUS Glidewires for coronary use with platinum (or gold) coil are operated manually or by a manual process.

DESIGN/MATERIALS

Parts	Terumo PTCA Wire	Cleared Terumo PTCA Wire K953533
Wire	Nickel-Titanium core coated with polyurethane	Nickel-Titanium core coated with polyurethane
Core Wire	Single Taper	Single Taper
Radiopaque Marker	Platinum or Gold	Platinum or Gold
Radiopaque Length	3-3.5cm	2cm
Exterior Coating	Hydrogel	Hydrogel

SPECIFICATIONS

Parts	Terumo PTCAWire	Cleared Terumo PTCA Wire K953533
Wire diameter	.014, .016, .018	.014, .016, .018
Wire length	180cm & 300cm	180cm & 300cm
Tip configuration	Straight	Straight

PERFORMANCE

The Terumo PTCA guide wires (represented in this submission) tested are substantially equivalent to the cleared Terumo RADIFOCUS® Glidewires® for coronary use with platinum (or gold) coil K953533. The Terumo PTCA guide wires represented in this submission exhibit a higher pushing resistance that can be associated with the higher crossability. For all other physical characteristics the Terumo PTCA guide wires represented in this submission were found to be equivalent to the cleared Terumo RADIFOCUS Glidewires for coronary use with platinum (or gold) coil K953533.

The following tests were performed demonstrating the substantial equivalence of the Terumo RADIFOCUS Glidewires for coronary use with platinum (or gold) coil submitted in this 510(k) to the cleared Terumo RADIFOCUS Glidewires for coronary use with platinum (or gold) coil K953533.

- Tensile Strength Test
- Torque Transmission Test
- Torque Failure Test
- Memory Retention Test
- Flexibility Test
- Radiopacity Test
- Pushing Resistence Test

PLEASE NOTE: A coating Adherence Strength Test and Coating Flake Test (SEM) was not performed again for purposes of this submission as none of the coating features of the Terumo PTCA guide wires represented in this submission are different from the cleared Terumo PTCA guide wires K953533.

ADDITIONAL SAFETY INFORMATION

Sterilization conditions have been validated according to the AAMI guidelines to provide a Sterility Assurance Level (SAL) of 10 to the negative sixth.

Ethylene oxide residuals will not exceed the maximum residue limits proposed for Part 821 of Title 21 in the Federal register of June 23, 1978 (or as finalized or amended).

Manufacturing control test methods include: functional, extraction and sterility tests.

Blood contacting materials were tested in accordance with the tests recommended in the Tripartite Biocompatibility Guidance for Medical Devices for biocompatibility testing of a device classified as Externally Communicating Devices, Blood Path Direct, Short-term (5 minutes-29 days). These tests were also in accordance with the tests recommended in the FDA General Program Memorandum #G95-1 (5/1/95): Use of International Standard ISO-10993, "Biological Evaluation of Medical Devices Part-1: Evaluation and Testing." [External Communicating Devices, Circulating Blood, Prolonged (24 hours-30 days) contact duration]. The blood contacting materials were found to be biocompatible.

The expiration dating for the RADIFOCUS® Glidewires® for coronary use with platinum (or gold) coil will be 24 months. This dating period is adopted from legally marketed Terumo guide wires cleared under K863138, K913074B and K925852A. The sterilization process and packaging materials are the same for these products. Verification testing of aged product consists of package permeability, sterility and shelf life functional testing.

CONCLUSION

The Terumo RADIFOCUS Glidewires for coronary use with platinum (or gold) coil submitted in this 510(k) are substantially equivalent in intended use, design, technology/principles of operation, materials and performance to the cleared Terumo RADIFOCUS Glidewires for coronary use with platinum (or gold) coil K953533. Differences between the devices cited in this section do not raise any new issues of safety or effectiveness.

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