TERUMO INTERVENTIONAL SYSTEMS

PUSHING BOUNDARIES

CROSSTELLA™ RX value analysis committee kit

product overview

product description

features and benefits

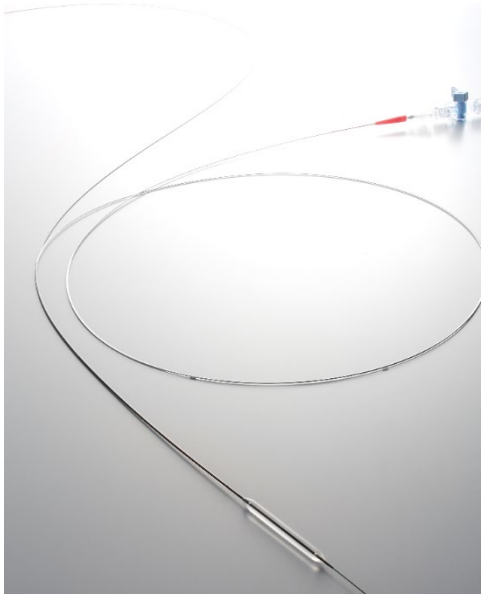
product description

Crosstella™ RX

Indications:
The CROSSTELLA RX PTA Balloon Dilatation Catheter is intended to dilate stenosis in the iliac, femoral, ilio-femoral, popliteal, infra-popliteal and renal arteries, and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae. This device is also indicated for stent post-dilatation in the peripheral vasculature.

Catheter design	Rapid Exchange
Range of diameters	2.0 mm – 6.0 mm
Range of lengths	20 mm – 200 mm
Guidewire compatibility	0.018"
Usable shaft length	90 cm, 150 cm, 200 cm
Balloon material	Nylon
Balloon folding diameter	Tri-fold (2.0 mm – 6.0 mm)
Hydrophilic coating	Yes
Shaft diameter	Distal: 4.0 Fr (1.32 mm) Proximal: 3.4 Fr (1.12 mm) or 4.1 Fr (1.35 mm)*
Sheath compatibility diameter	4 Fr (2.0 mm – 6.0 mm) 5 Fr (5.0 mm – 6.0 mm)
NP	8 atm
RBP	14 atm

** Depends on balloon dimensions*



features and benefits

1. Rapid exchange design for **increased efficiency** and **optimized control**[1]

2. Innovative shaft provides **excellent crossability**[1]

3. Engineered for **maximized pushability**[1]

4. Designed to deliver **rapid deflation**[1]

1. Data on file. Terumo Medical Corporation – CrosstellaRX_18_Product information_V1.

competitive information

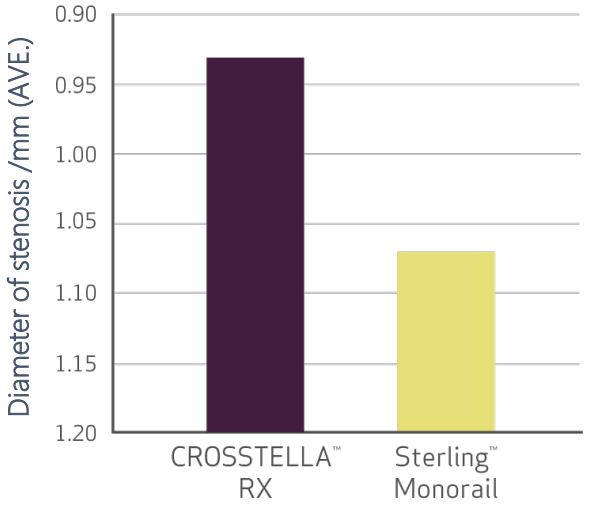
product design

competitive products comparison

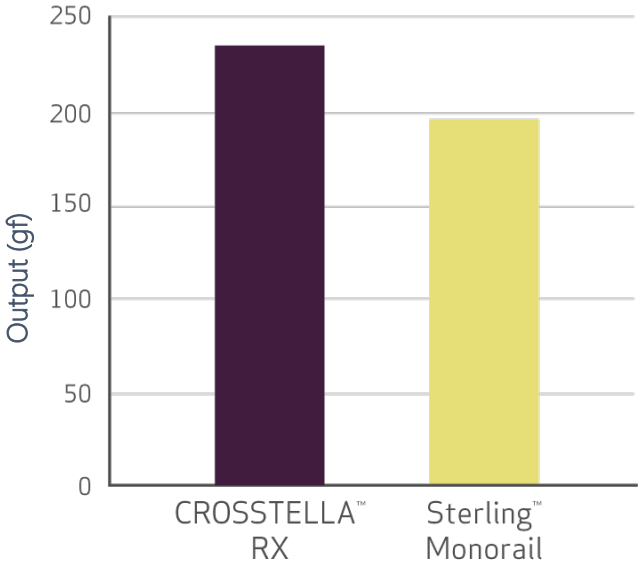
designed to maximize pushability and crossability

Innovative shaft construction for **enhanced crossability**[1]

- CROSSTELLA™ RX PTA Balloon Dilatation Catheter demonstrated excellent crossability when tested against a leading competitor*



Sample size: Terumo balloons RX n=10; Competitors n=5
Size used for comparison: 5mm x 40mm



Sample size: Terumo balloons n=10; Competitors n=5
Size used for comparison: 5mm x 40mm

Engineered to **maximize pushability**[1]

- End-to-end performance with a well-designed shaft and stiff tapered core wire

1. Data on file. Terumo Medical Corporation – CrosstellaRX_18_Product information_V1

*Tested against Boston Scientific Sterling™ Monorail™

Boston Scientific Sterling Monorail		CROSSTELLA RX
Semi-Compliant	Balloon Type	Semi- Compliant
Pebax	Balloon Material	Nylon
6	Nominal Pressure (atm)	8
14, 12	Rated Burst Pressure (atm)	14
0.018	Endhole (inch)	0.018
80, 90, 135, 150	Catheter Length (cm)	90, 150, 200
4, 5	Sheath Size (F)	4, 5
2, 2.5, 3, 3.5, 4, 4.5, 5, 5.5, 6, 6.5, 7, 8, 9, 10	Balloon Diameters (mm)	2, 2.5, 3, 4.0, 5.0, 6.0
10, 15, 20, 30, 40, 60, 80, 100, 120, 150, 200, 220	Balloon Lengths (mm)	20, 40, 60, 80, 100, 120, 150, 200

References: http://evtoday.com/buyers-guide/chart.asp?id=83#
https://www.bostonscientific.com/content/dam/bostonscientific/pi/portfolio-group/catheter-balloon/Sterling/Sterling%20Brochure.pdf/
Crosstella™ RX IFU, February 2016

materials management

ordering information

510(k) clearance letter

instructions for use

ordering information

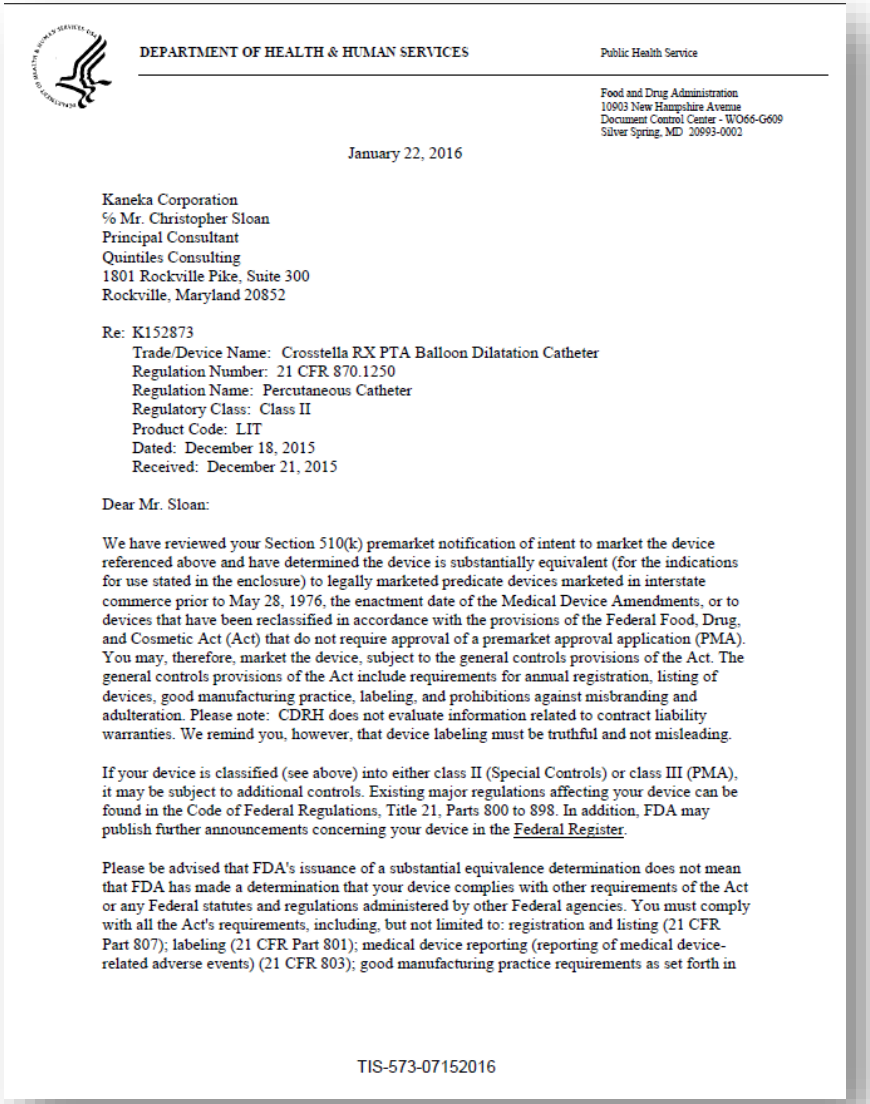
CROSSTELLA™ RX 0.018" PTA Balloon Dilatation Catheter – 90cm

BALLOON DIAMETER (mm)	BALLOON LENGTH (mm)								
	20	40	60	80	100	120	150	200	
2	BD-F20020MR	BD-F20040MR	BD-F20060MR	BD-F20080MR	BD-F20100MR	BD-F20120MR	BD-F20150MR	BD-F20200MR	4Fr
2.5	BD-F25020MR	BD-F25040MR	BD-F25060MR	BD-F25080MR	BD-F25100MR	BD-F25120MR	BD-F25150MR	BD-F25200MR	
3	BD-F30020MR	BD-F30040MR	BD-F30060MR	BD-F30080MR	BD-F30100MR	BD-F30120MR	BD-F30150MR	BD-F30200MR	
4	BD-F40020MR	BD-F40040MR	BD-F40060MR	BD-F40080MR	BD-F40100MR	BD-F40120MR	BD-F40150MR	BD-F40200MR	
5	BD-F50020MR	BD-F50040MR	BD-F50060MR	BD-F50080MR	BD-F50100MR	BD-F50120MR	BD-F50150MR	BD-F50200MR	5Fr
6	BD-F60020MR	BD-F60040MR	BD-F60060MR	BD-F60080MR	BD-F60100MR	BD-F60120MR	BD-F60150MR	BD-F60200MR	

CROSSTELLA™ RX 0.018" PTA Balloon Dilatation Catheter – 150cm

BALLOON DIAMETER (mm)	BALLOON LENGTH (mm)								
	20	40	60	80	100	120	150	200	
2	BD-F20020LR	BD-F20040LR	BD-F20060LR	BD-F20080LR	BD-F20100LR	BD-F20120LR	BD-F20150LR	BD-F20200LR	4Fr
2.5	BD-F25020LR	BD-F25040LR	BD-F25060LR	BD-F25080LR	BD-F25100LR	BD-F25120LR	BD-F25150LR	BD-F25200LR	
3	BD-F30020LR	BD-F30040LR	BD-F30060LR	BD-F30080LR	BD-F30100LR	BD-F30120LR	BD-F30150LR	BD-F30200LR	
4	BD-F40020LR	BD-F40040LR	BD-F40060LR	BD-F40080LR	BD-F40100LR	BD-F40120LR	BD-F40150LR	BD-F40200LR	
5	BD-F50020LR	BD-F50040LR	BD-F50060LR	BD-F50080LR	BD-F50100LR	BD-F50120LR	BD-F50150LR	BD-F50200LR	5Fr
6	BD-F60020LR	BD-F60040LR	BD-F60060LR	BD-F60080LR	BD-F60100LR	BD-F60120LR	BD-F60150LR	BD-F60200LR	

510(k) clearance letter



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

January 22, 2016

Kaneka Corporation
% Mr. Christopher Sloan
Principal Consultant
Quintiles Consulting
1801 Rockville Pike, Suite 300
Rockville, Maryland 20852

Re: K152873
Trade/Device Name: Crosstella RX PTA Balloon Dilatation Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: LIT
Dated: December 18, 2015
Received: December 21, 2015

Dear Mr. Sloan:

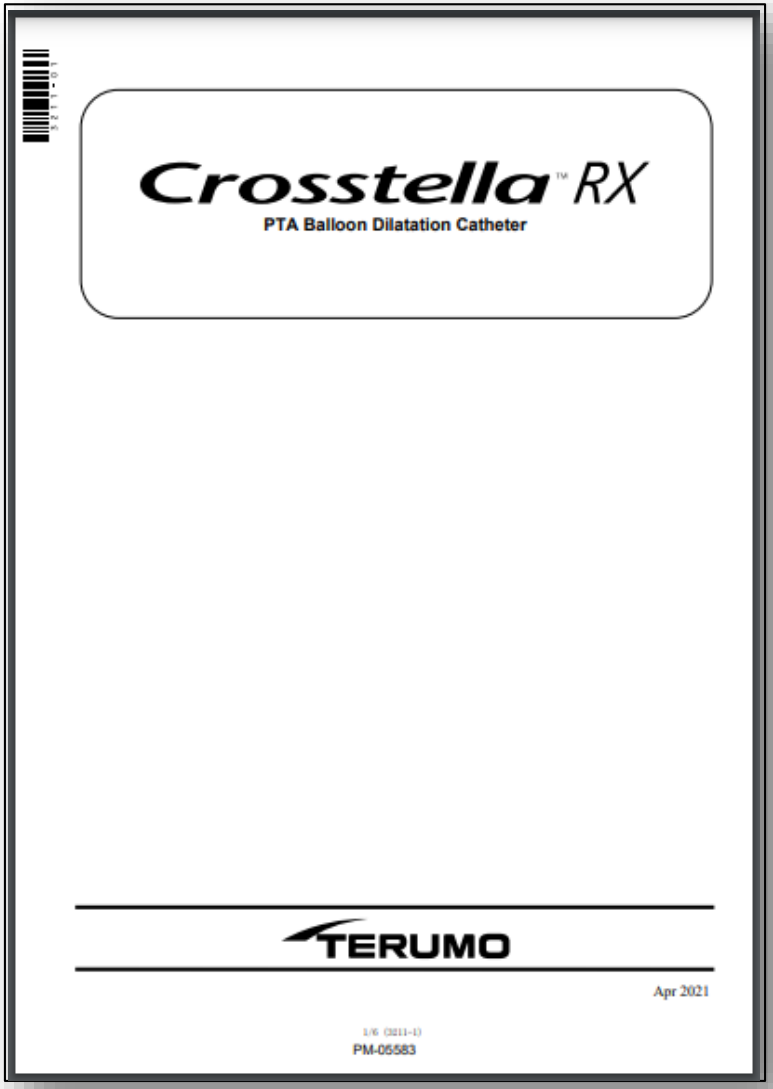
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May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

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

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

TIS-573-07152016

instructions for use



TERUMO INTERVENTIONAL SYSTEMS

PUSHING BOUNDARIES

CROSPERIO™ RX value analysis committee kit

product overview

product description

features and benefits

product description

Crosperio™ RX

Indications:
The CROSPERIO RX PTA Balloon Dilatation Catheter is intended to dilate stenosis in the iliac, femoral, ilio-femoral, popliteal, infra-popliteal and renal arteries, and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae. This device is also indicated for stent post-dilatation in the peripheral vasculature.

Catheter design	Rapid Exchange
Range of diameters	1.5 mm – 4.0 mm
Range of lengths	20 mm – 200 mm
Guidewire compatibility	0.014"
Usable shaft length	90 cm, 150 cm
Balloon material	Nylon
Balloon folding diameter	Tri-fold
Hydrophilic coating	Yes
Shaft diameter	Distal: 3.5 Fr (1.16 mm) Proximal: 3.5 Fr (1.16 mm)
Sheath compatibility diameter	4 Fr
NP	8 atm
RBP	14 atm

features and benefits

1

Rapid exchange design for **increased efficiency** and **optimized control**[1]

2

Engineered for **maximized pushability**[1]

3

Innovative shaft provides **excellent crossability**[1]

1. Data on file. Terumo Medical Corporation – CrosperioRX_14_Product information_V1.1 160308

competitive information

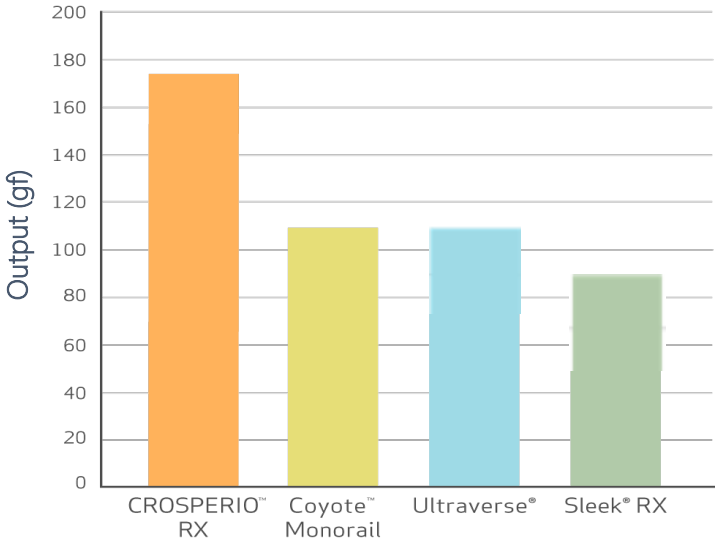
product design

competitive products comparison

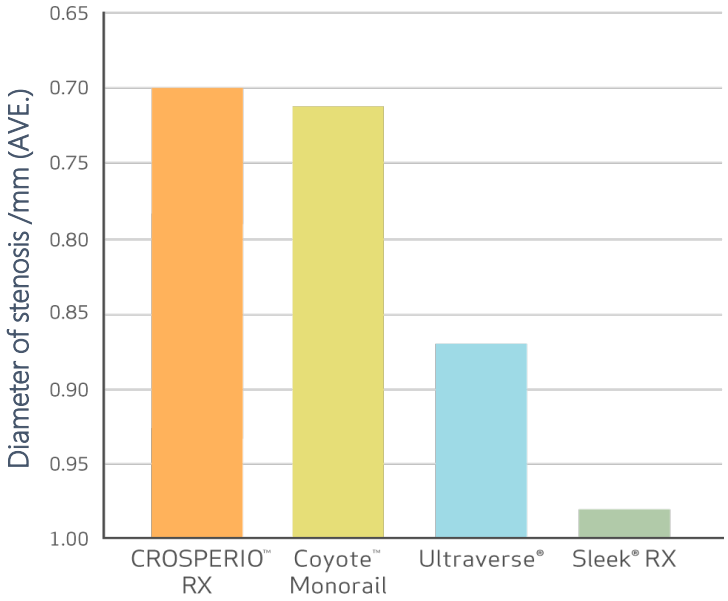
designed to maximize pushability and crossability

Engineered to **maximize pushability**[1]

- End-to-end performance with a well-designed shaft and stiff tapered core wire



Sample size: Terumo balloons RX n=10; Competitors n=5
Size used for comparison: 3mm x 40mm



Sample size: Terumo balloons n=10; Competitors n=5
Size used for comparison: 3mm x 40mm

Innovative shaft construction for **enhanced crossability**[1]

- CROSPERIO™ RX PTA Balloon Dilatation Catheter demonstrates excellent crossability*

1. Data on file. Terumo Medical Corporation – CrosperioRX_14_Product information_V1.1 160308

*Tested against select leading competitors

Boston Scientific Coyote Monorail		*CROSPERIO RX*
Not available	Balloon Type	Semi- Compliant
NyBax	Balloon Material	Nylon
8	Nominal Pressure (atm)	8
14	Rated Burst Pressure (atm)	14
0.014	Endhole (inch)	0.014
90, 150	Catheter Length (cm)	90, 150
4	Sheath Size (F)	4
1.5, 2, 2.5, 3, 3.5, 4	Balloon Diameters (mm)	1.5, 2, 2.5, 3, 3.5, 4
40, 60, 80, 100, 120, 150, 220	Balloon Lengths (mm)	20, 40, 80, 120, 150, 200

References: http://evtoday.com/buyers-guide/chart.asp?id=83#
http://www.bostonscientific.com/content/dam/bostonscientific/pi/portfolio-group/catheter-balloon/coyote/Coyote%20Brochure.pdf/
Crosperio™ RX IFU, February 2016

Bard Ultraverse RX		*CROSPERIO RX*
Not available	Balloon Type	Semi- Compliant
Not available	Balloon Material	Nylon
6	Nominal Pressure (atm)	8
Up to 16	Rated Burst Pressure (atm)	14
0.014	Endhole (inch)	0.014
150, 200	Catheter Length (cm)	90, 150
4, 5	Sheath Size (F)	4
1.25, 1.5, 2, 2.5, 3, 3.5, 4, 5, 6, 7	Balloon Diameters (mm)	1.5, 2, 2.5, 3, 3.5, 4
15, 20, 40, 60, 80, 100, 120, 150, 200, 250, 300	Balloon Lengths (mm)	20, 40, 80, 120, 150, 200

References: http://evtoday.com/buyers-guide/chart.asp?id=83#
https://www.accessdata.fda.gov/cdrh_docs/pdf13/K131199.pdf
Crosperio™ RX IFU, February 2016

Medtronic RapidCross RX		CROSPERIO RX
Semi-Compliant	Balloon Type	Semi- Compliant
Not available	Balloon Material	Nylon
8	Nominal Pressure (atm)	8
14	Rated Burst Pressure (atm)	14
0.014	Endhole (inch)	0.014
90, 170	Catheter Length (cm)	90, 150
4	Sheath Size (F)	4
1.5, 2, 2.5, 3, 3.5, 4	Balloon Diameters (mm)	1.5, 2, 2.5, 3, 3.5, 4
20, 40, 60, 80, 100, 120, 150, 210	Balloon Lengths (mm)	20, 40, 80, 120, 150, 200

References: http://evtoday.com/buyers-guide/chart.asp?id=83#
Crosperio™ RX IFU, February 2016
http://www.accessdata.fda.gov/cdrh_docs/pdf13/K130911.pdf

materials management

ordering information

510(k) clearance letter

instructions for use

ordering information

CROSPERIO™ RX 0.014" PTA Balloon Dilation Catheter – 90cm

BALLOON DIAMETER (mm)	BALLOON LENGTH (mm)					
	20	40	80	120	150	200
1.5	BD-B15020MR	BD-B15040MR	BD-B15080MR	BD-B15120MR	—	—
2	—	BD-B20040MR	BD-B20080MR	BD-B20120MR	BD-B20150MR	BD-B20200MR
2.5	—	BD-B25040MR	BD-B25080MR	BD-B25120MR	BD-B25150MR	BD-B25200MR
3	—	BD-B30040MR	BD-B30080MR	BD-B30120MR	BD-B30150MR	BD-B30200MR
3.5	—	BD-B35040MR	BD-B35080MR	BD-B35120MR	BD-B35150MR	BD-B35200MR
4	—	BD-B40040MR	BD-B40080MR	BD-B40120MR	BD-B40150MR	BD-B40200MR

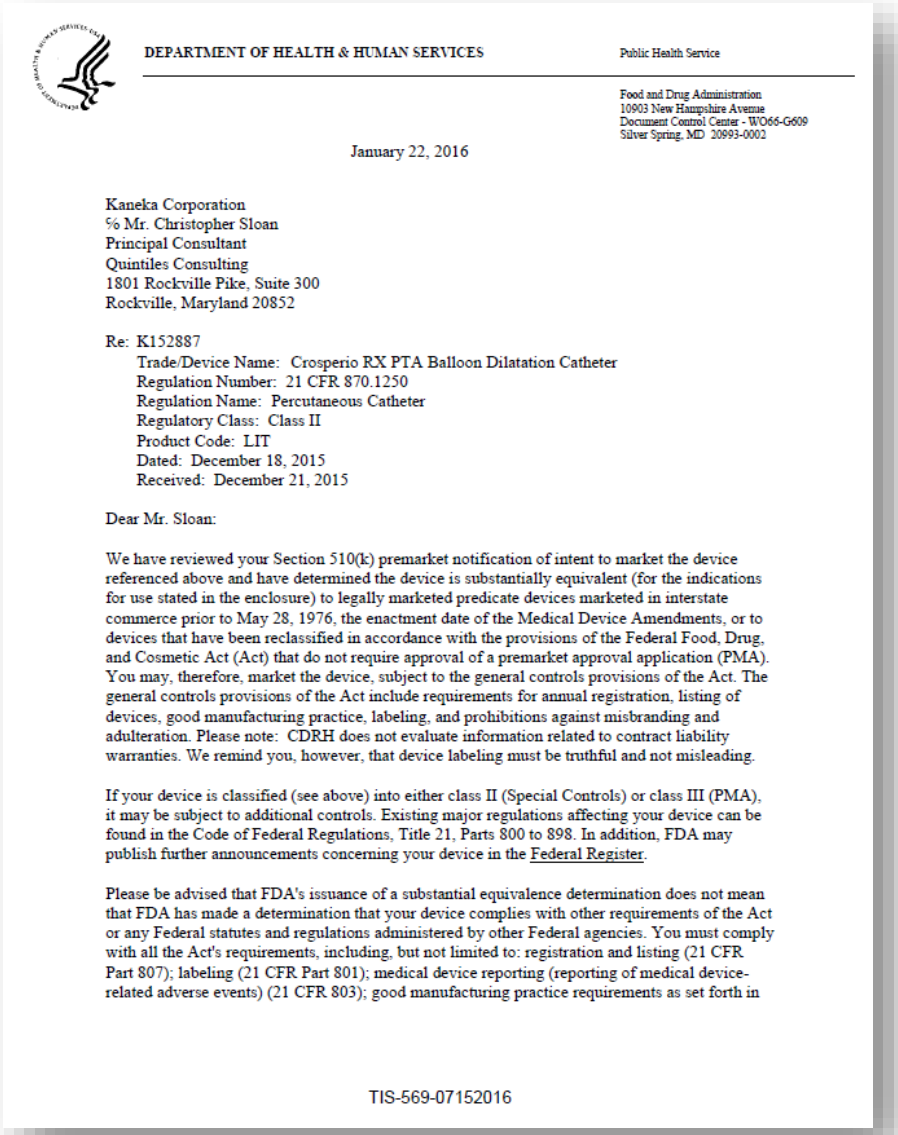
4Fr

CROSPERIO™ RX 0.014" PTA Balloon Dilation Catheter – 150cm

BALLOON DIAMETER (mm)	BALLOON LENGTH (mm)					
	20	40	80	120	150	200
1.5	BD-B15020LR	BD-B15040LR	BD-B15080LR	BD-B15120LR	—	—
2	—	BD-B20040LR	BD-B20080LR	BD-B20120LR	BD-B20150LR	BD-B20200LR
2.5	—	BD-B25040LR	BD-B25080LR	BD-B25120LR	BD-B25150LR	BD-B25200LR
3	—	BD-B30040LR	BD-B30080LR	BD-B30120LR	BD-B30150LR	BD-B30200LR
3.5	—	BD-B35040LR	BD-B35080LR	BD-B35120LR	BD-B35150LR	BD-B35200LR
4	—	BD-B40040LR	BD-B40080LR	BD-B40120LR	BD-B40150LR	BD-B40200LR

4Fr

510(k) clearance letter



DEPARTMENT OF HEALTH & HUMAN SERVICES — Public Health Service

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

January 22, 2016

Kaneka Corporation
% Mr. Christopher Sloan
Principal Consultant
Quintiles Consulting
1801 Rockville Pike, Suite 300
Rockville, Maryland 20852

Re: K152887
Trade/Device Name: Crosperio RX PTA Balloon Dilatation Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: LIT
Dated: December 18, 2015
Received: December 21, 2015

Dear Mr. Sloan:

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

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

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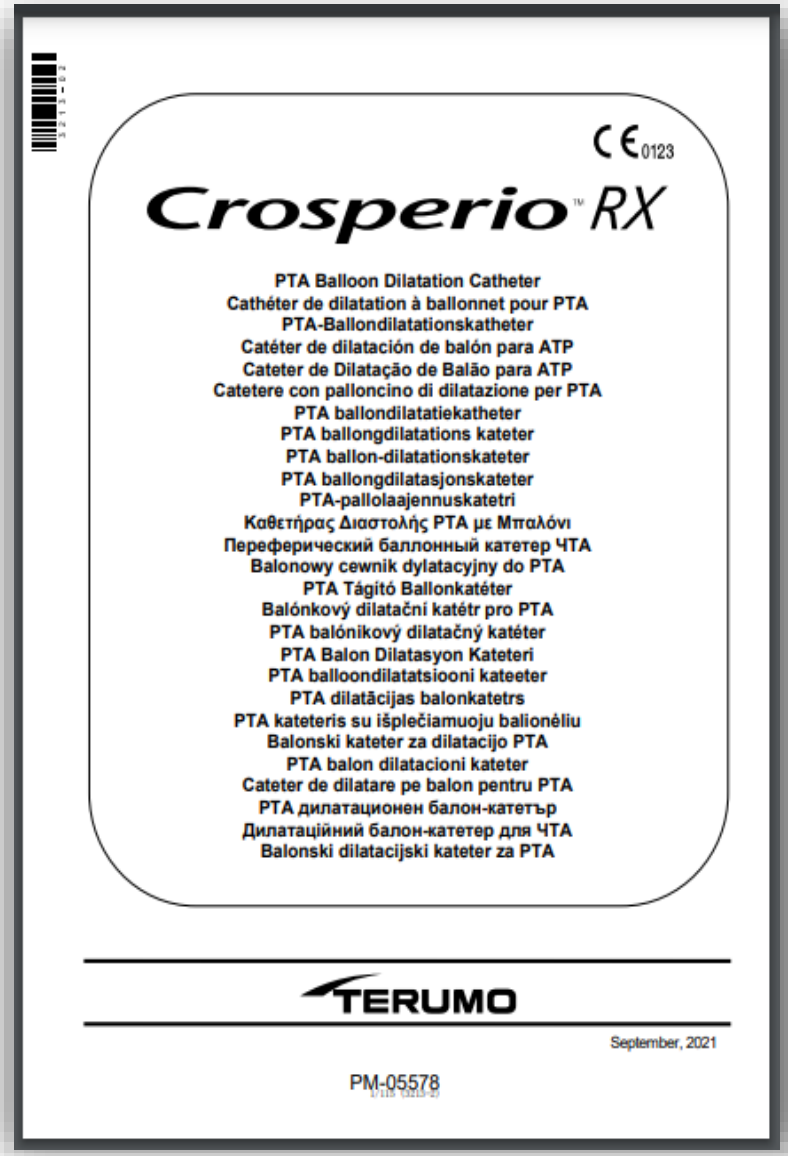
TIS-569-07152016

instructions for use



CE 0123

Crosperio™ RX

PTA Balloon Dilatation Catheter
Cathéter de dilatation à ballonnet pour PTA
PTA-Ballondilatationskatheter
Catéter de dilatación de balón para ATP
Cateter de Dilatação de Balão para ATP
Catetere con palloncino di dilatazione per PTA
PTA ballondilatatiekatheter
PTA ballongdilatations kateter
PTA ballon-dilatationskateter
PTA ballongdilatasjonskateter
PTA-pallolaajennuskatetri
Καθετήρας Διαστολής PTA με Μπαλόνι
Переферический баллонный катетер ЧТА
Balonowy cewnik dylatacyjny do PTA
PTA Tágító Ballonkatéter
Balónkový dilatační katétr pro PTA
PTA balónikový dilatačný katéter
PTA Balon Dilatasyon Kateteri
PTA balloondilatatsiooni kateeter
PTA dilatācijas balonkatetrs
PTA kateteris su išplečiamuoju balionėliu
Balonski kateter za dilatacijo PTA
PTA balon dilatacioni kateter
Cateter de dilatare pe balon pentru PTA
PTA дилатационен балон-катетър
Дилатаційний балон-катетер для ЧТА
Balonski dilatacijski kateter za PTA

TERUMO

September, 2021

PM-05578