Note: this medical device record is a supplement. The device description may have changed. Be sure to look at the original PMA to get an up-to-date view of this device.

Premarket Approval (PMA) Database

Trade Name	NOVOSTE BETA-CATH 3.5F SYSTEM
Classification Name	Intravascular Radiation Delivery System
Applicant	NOVOSTE CORP.
PMA Number	P000018
Supplement Number	S040
Date Received	12/16/2003
Decision Date	06/10/2004
Product Code	MOU
Advisory Committee	Cardiovascular
Supplement Type	Normal 180 Day Track
Supplement Reason	Change Design/components/specifications - Other
Expedited Review Granted?	No

Approval Order Statement Approval for the beta-rail 3. 5f delivery catheter with distal improvements, and a change in the procedure accessory pack.

Database Updated 5/05/2005

Note: this medical device record is a supplement. The device description may have changed. Be sure to look at the original PMA to get an up-to-date view of this device.

Premarket Approval (PMA) Database

Trade Name	NOVOSTE BETA-CATH SYSTEM
Classification Name	Intravascular Radiation Delivery System
Applicant	NOVOSTE CORP.
PMA Number	P000018
Supplement Number	S035
Date Received	08/21/2003
Decision Date	02/17/2004
Product Code	MOU
Advisory Committee	Cardiovascular
Supplement Type	Normal 180 Day Track
Supplement Reason	Change Design/components/specifications - Component
Expedited Review Granted?	No

α vi : 60mm, 3.5Fr
α V : CORONA, 5Fr

Approval Order Statement Approval for modifications to the alpha-series transfer devices (alpha iv, rev. 2, alpha v, and alpha vi), and modifications to the labeling for the beta-cath 5f and beta-cath 3. 5f systems.

αiv, R2 : 30/40mm, 3.5 Fr.

includes user-exchange battery (12 mo source)

Database Updated 5/05/2005

Note: this medical device record is a supplement. The device description may have changed. Be sure to look at the original PMA to get an up-to-date view of this device.

Premarket Approval (PMA) Database

Trade Name	BETA-CATH 3.5F SYSTEM - 60 MM
Classification Name	Intravascular Radiation Delivery System
Applicant	NOVOSTE CORP.
PMA Number	P000018
Supplement Number	S028
Date Received	01/06/2003
Decision Date	06/25/2003
Product Code	MOU
Advisory Committee	Cardiovascular
Supplement Type	Normal 180 Day Track
Supplement Reason	Change Design/components/specifications - Component
Expedited Review Granted?	No

Approval Order Statement Approval for the 60 mm beta-cath 3. 5f system. The device, as modified, is indicated to deliver beta radiation to the site of successful percutaneous coronary intervention (pci) for the treatment of in-stent restenosis in native coronary arteries with discrete lesions (treatable with a 20 mm balloon for the 30 mm and 40 mm systems and injury areas up to 40 mm for the 60 mm system) in a reference vessel diameter ranging from 2. 7 mm to 4. 0 mm.

Note: this medical device record is a supplement. The device description may have changed. Be sure to look at the original PMA to get an up-to-date view of this device.

Premarket Approval (PMA) Database

Trade Name	NOVOSTE 60 MM BETA-CATH 5 FR SYSTEM
Classification Name	Intravascular Radiation Delivery System
Applicant	NOVOSTE CORP.
PMA Number	P000018
Supplement Number	S018
Date Received	08/31/2001
Decision Date	03/25/2002
Product Code	MOU
Advisory Committee	Cardiovascular
Supplement Type	Normal 180 Day Track
Supplement Reason	Change Design/components/specifications - Component
Expedited Review Granted?	No

Approval Order Statement Approval for the novoste.

Database Updated 5/05/2005

Note: this medical device record is a supplement. The device description may have changed. Be sure to look at the original PMA to get an up-to-date view of this device.

Premarket Approval (PMA) Database

Trade Name	NOVOSTE BETA-CATH 3.5 FR SYSTEM
Classification Name	Intravascular Radiation Delivery System
Applicant	NOVOSTE CORP.
PMA Number	P000018
Supplement Number	S015
Date Received	07/31/2001
Decision Date	02/08/2002
Product Code	MOU
Advisory Committee	Cardiovascular
Supplement Type	Normal 180 Day Track
Supplement Reason	Change Design/components/specifications - Component
Expedited Review Granted?	No

Approval Order Statement Approval for the novoste beta-cath 3. 5 fr system. The novoste beta-cath 3. 5 fr system is indicated to deliver beta radiation to the site of successful percutaneous coronary intervention (pci) for the treatment of in-stent restenosis in native coronary arteries with discrete lesions (treatable with a 20 mm balloon) in a reference vessel diameter ranging from 2. 7 mm to 4. 0 mm.

Note: this medical device record is a supplement. The device description may have changed. Be sure to look at the original PMA to get an up-to-date view of this device.

Premarket Approval (PMA) Database

Trade Name	NOVOSTE(TM) BETA-CATH(TM) SYSTEM
Classification Name	Intravascular Radiation Delivery System
Generic Name	Intravascular Brachytherapy System
Applicant	NOVOSTE CORP.
PMA Number	P000018
Supplement Number	S011
Date Received	02/21/2001
Decision Date	08/22/2001
Product Code	MOU
Advisory Committee	Cardiovascular
Supplement Type	Real-time Process
Supplement Reason	Change Design/components/specifications - Other
Expedited Review Granted?	No

Approval Order Statement Approval for modifications to the design of the proximal marker of the source train.

Database Updated 5/05/2005

Note: this medical device record is a supplement. The device description may have changed. Be sure to look at the original PMA to get an up-to-date view of this device.

Premarket Approval (PMA) Database

Trade Name	NOVOSTE 40 MM BETA-CATH SYSTEM
Classification Name	Intravascular Radiation Delivery System
Generic Name	Intravascular Brachytherapy System
Applicant	NOVOSTE CORP.
PMA Number	P000018
Supplement Number	S005
Date Received	12/28/2000
Decision Date	06/15/2001
Product Code	MOU
Advisory Committee	Cardiovascular
Supplement Type	Real-time Process
Supplement Reason	Change Design/components/specifications - Specifications
Expedited Review Granted?	No

Approval Order Statement Approval for the novoste(tm) 40 mm beta-cath system. The novoste(tm) 40 mm beta-cath(tm) system is intended to deliver beta radiation to the site of successful percutaneous coronary intervention (pci) for the treatment of in-stent restenosis in native coronary arteries with discrete lesions (treatable with a 20 mm balloon) in a reference vessel diameter

New Search Back To Search Results

Note: this medical device has supplements. The device description may have changed. Be sure to look at the supplements to get an up-to-date view of this device.

Premarket Approval (PMA) Database

Trade Name	BETA-CATH (TM) SYSTEM
Classification Name	Intravascular Radiation Delivery System
Generic Name	Intravascular Brachytherapy System
Applicant	NOVOSTE CORP.
PMA Number	P000018
Date Received	04/17/2000
Decision Date	11/03/2000
Product Code	MOU
Docket Number	00M-1649
Notice Date	12/13/2000
Advisory Committee	Cardiovascular
Expedited Review Granted?	Yes
Information About:	Labeling, Approval Order, Summary Of Safety And Effectiveness

Approval Order Statement Approval for the beta-cath(tm) system. The device is indicated to deliver beta radiation to the site of successful percutaneous coronary intervention (pci) for the treatment of in-stent restenosis in native coronary arteries with discrete lesions (treatable with a 20 mm balloon) in a reference vessel diameter ranging from 2. 7 mm to 4. 0 mm.