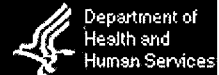


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Note: this medical device record is a supplement. The device description may have changed. Be sure to look at the [original PMA](#) to get an up-to-date view of this device.

### Premarket Approval (PMA) Database

<b>Trade Name</b>	NOVOSTE BETA-CATH 3.5F SYSTEM
<b>Classification Name</b>	<a href="#">Intravascular Radiation Delivery System</a>
<b>Applicant</b>	<a href="#">NOVOSTE CORP.</a>
<b>PMA Number</b>	P000018
<b>Supplement Number</b>	S040
<b>Date Received</b>	12/16/2003
<b>Decision Date</b>	06/10/2004
<b>Product Code</b>	MOU
<b>Advisory Committee</b>	Cardiovascular
<b>Supplement Type</b>	Normal 180 Day Track
<b>Supplement Reason</b>	Change Design/components/specifications - Other
<b>Expedited Review Granted?</b>	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

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### Premarket Approval (PMA) Database

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

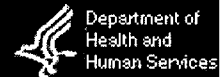
**Approval Order Statement** Approval for modifications to the alpha-series transfer devices (alpha iv, rev. 2, alpha v, and alpha vi), and modifications to the labeling for the beta-cath 5f and beta-cath 3. 5f systems.

*α vi: 60mm, 3.5 Fr*  
*α v: CORONA, 5 Fr*  
*α iv: 30/40mm, 3.5 Fr.*

*includes user-exchange battery  
(12 mo service)*

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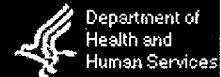
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Note: this medical device record is a supplement. The device description may have changed. Be sure to look at the [original PMA](#) to get an up-to-date view of this device.

### Premarket Approval (PMA) Database

<b>Trade Name</b>	BETA-CATH 3.5F SYSTEM - 60 MM
<b>Classification Name</b>	<u>Intravascular Radiation Delivery System</u>
<b>Applicant</b>	<u>NOVOSTE CORP.</u>
<b>PMA Number</b>	P000018
<b>Supplement Number</b>	S028
<b>Date Received</b>	01/06/2003
<b>Decision Date</b>	06/25/2003
<b>Product Code</b>	MOU
<b>Advisory Committee</b>	Cardiovascular
<b>Supplement Type</b>	Normal 180 Day Track
<b>Supplement Reason</b>	Change Design/components/specifications - Component
<b>Expedited Review Granted?</b>	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.

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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

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

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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.

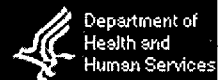
### Premarket Approval (PMA) Database

<b>Trade Name</b>	NOVOSTE BETA-CATH 3.5 FR SYSTEM
<b>Classification Name</b>	<a href="#">Intravascular Radiation Delivery System</a>
<b>Applicant</b>	<a href="#">NOVOSTE CORP.</a>
<b>PMA Number</b>	P000018
<b>Supplement Number</b>	S015
<b>Date Received</b>	07/31/2001
<b>Decision Date</b>	02/08/2002
<b>Product Code</b>	MOU
<b>Advisory Committee</b>	Cardiovascular
<b>Supplement Type</b>	Normal 180 Day Track
<b>Supplement Reason</b>	Change Design/components/specifications - Component
<b>Expedited Review Granted?</b>	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.



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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

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

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

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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

<b>Trade Name</b>	NOVOSTE 40 MM BETA-CATH SYSTEM
<b>Classification Name</b>	<a href="#">Intravascular Radiation Delivery System</a>
<b>Generic Name</b>	Intravascular Brachytherapy System
<b>Applicant</b>	<a href="#">NOVOSTE CORP.</a>
<b>PMA Number</b>	P000018
<b>Supplement Number</b>	S005
<b>Date Received</b>	12/28/2000
<b>Decision Date</b>	06/15/2001
<b>Product Code</b>	MOU
<b>Advisory Committee</b>	Cardiovascular
<b>Supplement Type</b>	Real-time Process
<b>Supplement Reason</b>	Change Design/components/specifications - Specifications
<b>Expedited Review Granted?</b>	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

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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

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

**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.