

DEVICE INFORMATION

Type of device:

Device manufacturer's name:

Device manufacturer's street address: (Line 1)

Street address: (Line 2)

City:

State:
(Please limit your response to 2 characters)

Zip:

Device brand name:

Approximate age of device:
Years

If a disposable device, was the packaging saved? [Optional]

Yes No
 Not known Not applicable

Is this a single use device that was reprocessed and reused on a patient?

Yes No
 Unknown

Is this a laboratory device or laboratory test?

Yes No

Device serial #:
(Please limit your response to 30 characters)

Device model #:

Device lot #:
(Please limit your response to 30 characters)

Device catalog (REF) #:
(Please limit your response to 30 characters)

Other device #:

Expiration date: (mm/dd/yyyy)

If the device was implanted, give implant date: (mm/dd/yyyy)

If the device was explanted, give explant date: (mm/dd/yyyy)

Was the device returned to the manufacturer?

Yes No
 Not known Not applicable

Is the device involved in this event available at your facility for evaluation?

Yes No
 Not known Not applicable

Have you made the manufacturer aware of this problem/issue?

Yes No
 Unknown

Unique Device Identifier (UDI):

Cancel

Save »