



## CALIFORNIA DEVICE RECALL INFORMATION SHEET

### Abbott Medical Recalls Implantable Pulse Generator (Ipg) For Complaints From Patients Who Are Unable To Exit Mri (Magnetic Resonance Imaging) Mode On Their Ipgs

Recall Date	Product Description	Recalling Firm	Recall Reason
9/20/2023	<b>Abbott Medical</b> Proclaim XR 5 Implantable Pulse Generator REF 3660	<b>Abbott Medical</b> Plano, Texas	Firm has received complaints from patients who are unable to exit MRI (Magnetic Resonance Imaging) mode on their IPGs
9/20/2023	<b>Abbott Medical</b> Proclaim" XR 7 Implantable Pulse Generator REF 3662	<b>Abbott Medical</b> Plano, Texas	Firm has received complaints from patients who are unable to exit MRI (Magnetic Resonance Imaging) mode on their IPGs
9/20/2023	<b>Abbott Medical</b> Proclaim Plus 5 Implantable Pulse Generator REF 3670	<b>Abbott Medical</b> Plano, Texas	Firm has received complaints from patients who are unable to exit MRI (Magnetic Resonance Imaging) mode on their IPGs
9/20/2023	<b>Abbott Medical</b> Proclaim Plus 7 Implantable Pulse Generator REF 3672	<b>Abbott Medical</b> Plano, Texas	Firm has received complaints from patients who are unable to exit MRI (Magnetic Resonance Imaging) mode on their IPGs

9/20/2023	<b>Abbott Medical</b> Proclaim DRG Implantable Pulse Generator REF 3664	<b>Abbott Medical</b> Plano, Texas	Firm has received complaints from patients who are unable to exit MRI (Magnetic Resonance Imaging) mode on their IPGs
9/20/2023	<b>Abbott Medical</b> Infinity 5 Implantable Pulse Generator REF 6660	<b>Abbott Medical</b> Plano, Texas	Firm has received complaints from patients who are unable to exit MRI (Magnetic Resonance Imaging) mode on their IPGs

<b>Recall Class</b>	<b>Product Identification</b>	<b>Distribution</b>	<b>Affected Dates</b>
I	<b>Abbott Medical</b> Proclaim XR 5 Implantable Model Number: 3660 UDI-DI Codes: 05415067031419 05415067020192	95,226 Units Nationwide including California	July 2023 and prior
I	<b>Abbott Medical</b> Proclaim" XR 7 Implantable Model Number: 3662 UDI-DI Codes: 05415067031426 05415067020222	32,782 Units Nationwide including California	July 2023 and prior
I	<b>Abbott Medical</b> Proclaim Plus 5 Implantable Model Number: 3670 UDI-DI Codes: 05415067046383	2,242 Units Nationwide including California	July 2023 and prior
I	<b>Abbott Medical</b> Proclaim Plus 7 Implantable Pulse Generator REF 3672 Model Number: 3672 UDI-DI Codes: 05415067046406	387 Units Nationwide including California	July 2023 and prior

I	<b>Abbott Medical</b> Proclaim DRG Implantable Pulse Generator REF 3664 Model Number 3664 UDI-DI Codes: 05415067020215	12,134 Units Nationwide including California	July 2023 and prior
I	<b>Abbott Medical</b> Infinity 5 Implantable Pulse Generator REF 6660 Model Number: 6660 UDI-DI Codes: 05415067030016	4,464 Units Nationwide including California	July 2023 and prior

FOR ADDITIONAL INFORMATION, PLEASE VISIT THE [FDA WEBSITE](#)

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