

California Device Recall Information Sheet

Food and Drug Branch – Device Recalls

KCI USA, INC. 3M V.A.C. VIA Negative Pressure Wound Therapy System and 3M Prevena Plus 125 Therapy Unit and System Kits

Recall Date	Product Description	Recalling Firm	Recall Reason
02/14/2025	3M V.A.C. VIA Negative Pressure Wound Therapy System REF: VIAKIT077D01/US V.A.C. VIA 7 Day Kit VIAKIT07S05/AU V.A.C. VIA Starter Kit 65-Pack VIAKIT077D01/GB V.A.C. VIA 7 Day Kit, Single Shipper 3M Prevena Plus 125 Therapy Unit and System Kits REF: PRE3021US Prevena Plus Duo Peel and Place 20cm System Kit, US PRE3201US Prevena Plus Peel and Place 35 cm system Kit, US PRE3201 Prevena Plus Peel and Place 35 cm system Kit PRE4000US Prevena Plus 125 Therapy Unit, US PRE4001AU	KCI USA, INC.	Due to increase in complaints related to leak alarms

	PREVENA PLUS SYSTEM KIT, AU PRE4001CA		
	PREVENA PLUS SYSTEM KIT, CA PRE4001UK		
	PREVENA PLUS SYSTEM KIT, UK PRE4001US		
	PREVENA PLUS SYSTEM KIT, US PRE4001		
	PREVENA PLUS SYSTEM KIT PRE4001ZA		
	PREVENA PLUS SYSTEM KIT, ZA PRE4010		
	PREVENA PLUS STANDALONE EXTENDED LIFE SYSTEM KIT PRE5001		
	PREVENA RESTOR ARTHRO- FORM SYSTEM KIT 33X30 CM PRE5101		
	PREVENA RESTOR ARTHRO- FORM SYSTEM KIT 46X30 CM PRE5221		
	PREVENA RESTOR BELLA- FORM SYSTEM KIT 21X19 CM PRE5321		
	PREVENA RESTOR BELLA- FORM SYSTEM KIT 24X22 CM PRE5421		
	PREVENA RESTOR BELLA- FORM SYSTEM KIT 29X27 CM PRE5501		
	PREVENA RESTOR AXIO- FORM SYSTEM KIT 29X28 CM		

Recall Class	Product Identification	Distribution	Affected Dates
II	VIAKIT077D01/US V.A.C. VIA 7 DAY KIT UDI-DI code: 00849554002388 Assembly Item Number: VIAKIT077D01/USV003 Lot Numbers: C17525V003 C17557V003 VIAKIT07S05/AU V.A.C. VIA STARTER KIT 5-PACK UDI-DI code: 00849554002401 Assembly Item Number: VIAKIT07S05/AUV003 Lot Number: C16937V003 VIAKIT077D01/GB V.A.C. VIA 7 DAY KIT, SINGLE SHIPPER UDI-DI code: 00849554002364 Assembly Item Number: VIAKIT077D01/GBV003 Lot Numbers: C16936V003 C17027V003 PRE3021US Prevena Plus Duo Peel and Place 20cm System Kit, US UDI-DI code: 00849554006744 Assembly Item number: PRE3021USV005 Lot Numbers: C16793V005 C17567V005 C18503V005 PRE3201US Prevena Plus Peel and Place 35 cm system Kit, US UDI-DI code: 00849554006621 Assembly Item Number: PRE3201USV006 Lot Numbers: C16794V006 C17165V006 C17569V006 C17954V006 C18502V006 C18610V006 C19238V006 Assembly Item Number: PRE3201USV007 Lot Numbers: C18068V007 C18504V007	7,953 units in California	January and prior

	PRE3201 Prevena Plus Peel and Place 35 cm system Kit UDI-DI code: 00849554006645 Assembly Item Number: PRE3201V008 Lot Numbers: C17273V008 C17882V008 C18391V008 C19240V008 Assembly Item Number: PRE3201V009 Lot Numbers: C16796V009 C17755V009 C17955V009 Assembly Item Numbers: PRE3201V010 Lot Numbers: C16797V010 C17956V010 C18505V010 Assembly Item Number: PRE3201V011 Lot Numbers: C16798V011 C17957V011 C18506V011 PRE4000US Prevena Plus 125 Therapy Unit, US UDI-DI code: 00849554006768 Assembly Item Number: PRE4000USV005 Lot Numbers: C17175V005 C17884V005 Assembly Item Number: PRE4000USV008 Lot Numbers: C16801V008 C16874V008 C16998V008 C17030V008 C17133V008 C17183V008 C17405V008 C17541V008 C17574V008 C17757V008 C17779V008 C17878V008 C17951V008 C18057V008 C18149V008 C18208V008 C18392V008 C18444V008 C18719V008 C18723V008 C18810V008 C18860V008 C18956V008 C19159V008 C19232V008 PRE4001AU PREVENA PLUS SYSTEM KIT, AU UDI-DI code: 00849554005877		
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	Assembly Item Number: PRE4001AUV006 Lot Numbers: C16680V006 C17886V006 C18461V006 C18813V006 PRE4001CA PREVENA PLUS SYSTEM KIT, CA UDI-DI code: 00849554005891 Assembly Item Number: PRE4001CAV006 Lot Numbers: C17683V006 C17818V006 C19162V006 PRE4001UK PREVENA PLUS SYSTEM KIT, UK UDI-DI code: 00849554005907 Assembly Item Number: PRE4001UKV006 Lot Numbers: C17024V006 C17177V006 C17300V006 C17958V006 PRE4001US PREVENA PLUS SYSTEM KIT, US UDI-DI code: 00849554005365 Assembly Item Number: PRE4001USV005 Lot Number: C18959V005 Assembly Item Number: PRE4001USV006 Lot Numbers: C16753V006 C16802V006 C16875V006 C16999V006 C17032V006 C17129V006 C17184V006 C17258V006 C17303V006 C17406V006 C17565V006 C17576V006 C17780V006 C17879V006 C17952V006 C18058V006 C18205V006 C18227V006 C18394V006 C18466V006 C18721V006 C18725V006 C18812V006 C18862V006 C18958V006 C19060V006 C19161V006 C19234V006 PRE4001 PREVENA PLUS		
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	SYSTEM KIT Assembly Item Number: PRE4001V006 Lot Numbers: C17178V006 C18062V006 C18814V006 Assembly Item Number: PRE4001V008 Lot Number: C18523V008 PRE4001ZA PREVENA PLUS SYSTEM KIT, ZA UDI-DI code: 00849554005884 Assembly Item Number: PRE4001ZAV006 Lot Numbers: C18060V006 C18464V006 PRE4010 PREVENA PLUS STANDALONE EXTENDED LIFE SYSTEM KIT UDI-DI code: 00849554007819 Assembly Item Number: PRE4010V001 Lot Numbers: C16715V001 C16883V001 C17000V001 C17031V001 C17134V001 C17195V001 C17257V001 C17302V001 C17407V001 C17542V001 C17575V001 C17758V001 C17781V001 C17880V001 C17953V001 C18059V001 C18150V001 C18209V001 C18393V001 C18465V001 C18720V001 C18724V001 C18811V001 C18861V001 C18957V001 C19059V001 C19160V001 Assembly Item Number: PRE4010V003 Lot Number: C16878V003 Assembly Item Number: PRE4010V004 Lot Numbers: C16879V004 C17684V004 Assembly Item Number: PRE4010V005 Lot Numbers: C17007V005 C17534V005 C17959V005		
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	Assembly Item Number: PRE4010V007 Lot Number: C18815V007 Assembly Number: PRE4010V016 UDI-DI codes: Shipper: 50849554014096 Primary Box: 00849554014091 Lot Numbers: C16880V016 C17179V016 C17685V016 C17960V016 C18445V016 C18816V016 Assembly Item Number: PRE4010V017 UDI-DI Codes: Shipper: 50849554014102 Primary Box: 00849554014107 Lot Numbers: C16881V017 C17180V017 C17304V017 C17686V017 C17961V017 C18446V017 C18817V017 Assembly Item Number: PRE4010V018 UDI-DI codes: PRE4010V018 - Shipper: 50849554014119 Primary Box: 00849554014114 Lot Numbers: C18077V018 C18863V018 Assembly Item Number: PRE4010V019 UDI-DI codes: PRE4010V019 – Shipper: 50849554014126 Primary Box: 00849554014121 Lot Numbers: C17181V019 C17687V019 C18447V019 Assembly Item Number: PRE4010V020 UDI-DI codes: PRE4010V020 – Shipper: 50849554014133 Primary Box: 00849554014138 Lot Numbers: C16882V020 C17182V020 C17307V020 C17688V020 C18061V020		
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	C18448V020 C18818V020 Assembly Item Number: PRE4010V021 UDI-DI codes: PRE4010V021 – Shipper: 50849554014140 Primary Box: 00849554014145 Lot Numbers: C17305V021 C18819V021 Assembly Item Number: PRE4010V023 UDI-DI codes: PRE4010V023 – Shipper: 50849554014355 Primary Box: 00849554014350 Lot Number: C18820V023 PRE5001 PREVENA RESTOR ARTHRO-FORM SYSTEM KIT 33X30 CM UDI-DI code: 00849554006805 Assembly Item Number: PRE5001V001 Lot Numbers: C16928V001 C17196V001 C17759V001 C18578V001 C18625V001 C19061V001 Assembly Item Number: PRE5001V002 Lot Numbers: C16748V002 C17760V002 Assembly Item Number: PRE5001V003 Lot Numbers: C16749V003 C16929V003 Assembly Item Number: PRE5001V004 Lot Numbers: C16750V004 C18626V004 C19062V004 Assembly Item Number: PRE5001V005 Lot Numbers: C16930V005 C17761V005 C18069V005 PRE5101 PREVENA RESTOR ARTHRO-FORM SYSTEM KIT 46X30 CM UDI-DI code: 00849554007116		
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	Assembly Item Number: PRE5101V001 Lot Number: C17762V001 Assembly Item Number: PRE5101V002 Lot Number: C17763V002 Assembly Item Number: PRE5101V003 Lot Number: C17219V003 Assembly Item Number: PRE5101V004 Lot Numbers: C17765V004 C18070V004 Assembly Item Number: PRE5101V005 Lot Numbers: C18072V005 C18627V005 PRE5221 PREVENA RESTOR BELLA- FORM SYSTEM KIT 21X19 CM UDI-DI code: 00849554007154 Assembly Item Number: PRE5221V001 Lot Numbers: C18579V001 C18628V001 C19064V001 Assembly Item Number: PRE5221V002 Lot Numbers: C16931V002 C17220V002 Assembly Item Number: PRE5221V004 Lot Numbers: C18580V004 C18782V004 C19066V004 Assembly Item Number: PRE5221V005 Lot Numbers: C17221V005 C17767V005 C18783V005 PRE5321 PREVENA RESTOR BELLA-FORM SYSTEM KIT 24X22 CM UDI-DI code: 00849554007178 Assembly Item Number: PRE5321V001 Lot Numbers: C18612V001 C18803V001 Assembly Item Number: PRE5321V002		
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	Lot Numbers: C18613V002 C18613V002 Assembly Item Numbers: PRE5321V003 Lot Numbers: C16751V003 C18614V003 Assembly Item Number: PRE5321V004 Lot Numbers: C18615V004 C19538V004 Assembly Item Number: PRE5321V005 Lot Number: C18616V005 PRE5421 PREVENA RESTOR BELLA-FORM SYSTEM KIT 29X27 CM UDI-DI code: 00849554007130 Assembly Item Number: PRE5421V001 Lot Numbers: C16932V001 C17222V001 C17768V001 C18073V001 C18581V001 C18784V001 C19067V001 Assembly Item Number: PRE5421V002 Lot Numbers: C16933V002 C17223V002 Assembly Item Number: PRE5421V003 Lot Numbers: C17224V003 C17770V003 C18074V003 C18583V003 Assembly Item Number: PRE5421V004 Lot Numbers: C16752V004 C16934V004 C17225V004 C17771V004 C18584V004 Assembly Item Number: PRE5421V005 Lot Numbers: C18585V005 C19068V005 PRE5501 PREVENA RESTOR AXIO- FORM SYSTEM KIT 29X28 CM UDI-DI code: 00849554007826 Assembly Item Number: PRE5501V001		
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	Lot Numbers: C16935V001 C18076V001 C18586V001 PRE6001 PREVENA RESTOR ADAPTI-FORM SYSTEM KIT UDI-DI code: Pending Assembly Item Number: Pending Lot Numbers: Pending		
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For additional information, please visit: [FDA Website \(V.A.C\)](#) and [FDA Website \(Prevena Plus\)](#).