

California Device Recall Information Sheet

Food and Drug Branch – Device Recalls

Zyno Medical LLC Recalls Z-800 Infusion System.

Recall Date	Product Description	Recalling Firm	Recall Reason
6/6/25	Z-800 Infusion System. Intended to provide intravenous infusion of parenteral fluids, blood, and blood products to a patient.	Zyno Medical LLC	Unreleased software versions were installed on distributed devices without verification or validation.
6/6/25	Z-800WF Infusion System. Intended to provide intravenous infusion of parenteral fluids, blood, and blood products to a patient.	Zyno Medical LLC	Unreleased software versions were installed on distributed devices without verification or validation.
6/6/25	Z-800W Infusion System. Intended to provide intravenous infusion of parenteral fluids, blood, and blood products to a patient.	Zyno Medical LLC	Unreleased software versions were installed on distributed devices without verification or validation.
6/6/25	Z-800F Infusion System. Intended to provide intravenous infusion of parenteral fluids, blood, and blood products to a patient.	Zyno Medical LLC	Unreleased software versions were installed on distributed devices without verification or validation.

Recall Class	Product Identification	Distribution	Affected Dates
I	Lot Code: Model Number; Z800; UDI-DI: 00814377102006; Serial No.: 800242; 801925; 802867;	613 Units Nationwide	May 2025 and prior.

900875; 901058; 901089; 901101; 901126; 901143; 901567; 904021; 904073; 800378; 801950; 803020; 900914; 901061; 901090; 901102; 901129; 901145; 901795; 904023; 904083; 801082; 802113; 803268; 900961; 901066; 901091; 901103; 901130; 901230; 904004; 904026; 904087; 801353; 802131; 803526; 900964; 901070; 901092; 901110; 901131; 901240; 904006; 904027; 904093; 801420; 802160; 803768; 901001; 901076; 901093; 901112; 901132; 901241; 904007; 904028; 904094; 801503; 802645; 900029; 901014; 901077; 901094; 901113; 901133; 901244; 904009; 904029; 905077; 801601; 802753; 900035; 901024; 901081; 901095; 901115; 901134; 901245; 904011; 904030; 905162; 801640; 802764; 900051; 901041; 901083; 901096; 901116; 901136; 901246; 904012; 904031; 906681; 801852; 802771; 900115; 901054; 901085; 901097; 901117; 901138; 901249; 904013; 904038; 906692; 801855; 802774; 900133; 901055; 901086; 901098; 901118; 901140; 901250; 904014; 904040; 906693; 801881; 802780; 900147; 901056; 901087; 901099; 901119; 901141; 901252; 904018; 904042; 906716; 801884; 802798; 900569; 901057; 901088; 901100; 901123; 901142; 901255; 904020; 904053; 906720; 906721.		
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I	Model No. Z800WF; UDI-DI: 00814371020037; Serial No. 500004; 500005; 500006; 500810; 500812; 500813; 501748; 503680; 503681; 503682.	613 Units Nationwide	May 2025 and prior.
I	Model Number: Z800W; UDI-DI; 00814371020020; Serial No. 700063; 700163; 700203; 700402; 700488; 700093; 700169; 700210; 700428; 700495; 700104; 700172; 700214; 700431; 700503; 700111; 700188; 700225; 700440; 700510; 700120; 700189; 700230; 700449; 700513; 700135; 700190; 700285; 700460; 700541; 700145; 700192; 700375; 700471; 700481; 700150; 700195; 700391; 700472; 700397; 700159; 700199; 700393; 700478; 700201; 700162.	613 Units Nationwide	May 2025 and prior.
I	Model No: Z800F; UDI-DI: 00814371020013; Serial No. 600091; 600133; 600203; 600259; 600320; 600361; 600404; 600446; 600482; 600526; 600565; 600601; 600094; 600138; 600204; 600261; 600321; 600362; 600406; 600447; 600483; 600528; 600566; 600603; 600095; 600139; 600206; 600262; 600322; 600363; 600407; 600449; 600485; 600529; 600568; 600604; 600099; 600141; 600207; 600263; 600323; 600364; 600408; 600450; 600487; 600531; 600569; 600605; 600100; 600142; 600209; 600265; 600324; 600369; 600410; 600451; 600488; 600532; 600570; 600608; 600102; 600143; 600211; 600266; 600325; 600370;	613 Units Nationwide	May 2025 and prior.

600411; 600452; 600489; 600533; 600571; 600609; 600104; 600146; 600215; 600267; 600326; 600376; 600412; 600453; 600490; 600535; 600572; 600610; 600105; 600148; 600217; 600268; 600328; 600377; 600414; 600454; 600495; 600536; 600573; 600611; 600106; 600150; 600220; 600270; 600330; 600378; 600415; 600456; 600496; 600539; 600574; 600612; 600108; 600151; 600223; 600271; 600331; 600379; 600416; 600457; 600498; 600540; 600575; 600613; 600109; 600152; 600224; 600289; 600335; 600383; 600417; 600458; 600499; 600541; 600576; 600614; 600110; 600153; 600227; 600292; 600336; 600384; 600418; 600460; 600504; 600542; 600577; 600615; 600111; 600154; 600228; 600294; 600338; 600385; 600419; 600461; 600505; 600543; 600578; 600617; 600112; 600155; 600229; 600295; 600339; 600386; 600422; 600462; 600506; 600545; 600579; 600618; 600113; 600156; 600230; 600297; 600341; 600387; 600423; 600464; 600509; 600546; 600580; 600921; 600114; 600157; 600231; 600298; 600342; 600388; 600424; 600465; 600510; 600549; 600583; 601325; 600115; 600158; 600235; 600299; 600343; 600389; 600425; 600466; 600511; 600551; 600584; 601433; 600116; 600159; 600238; 600300; 600344; 600391;		
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600427; 600467; 600513; 600553; 600585; 601514; 600118; 600160; 600239; 600301; 600347; 600392; 600430; 600470; 600514; 600554; 600586; 601603; 600120; 600161; 600240; 600302; 600348; 600393; 600431; 600471; 600516; 600555; 600587; 601651; 600121; 600162; 600249; 600303; 600349; 600394; 600432; 600473; 600517; 600556; 600589; 602578; 600122; 600164; 600250; 600304; 600350; 600396; 600436; 600474; 600518; 600557; 600591; 602743; 600126; 600165; 600251; 600305; 600351; 600398; 600437; 600475; 600519; 600558; 600592; 602807; 600127; 600168; 600252; 600306; 600352; 600399; 600438; 600476; 600520; 600559; 600594; 603858; 600129; 600174; 600253; 600308; 600353; 600400; 600440; 600477; 600521; 600560; 600595; 604637; 600130; 600176; 600254; 600309; 600356; 600401; 600442; 600478; 600522; 600562; 600596; 605411; 600131; 600188; 600255; 600310; 600357; 600402; 600443; 600480; 600523; 600563; 600599; 605870; 600132; 600192; 600257; 600319; 600359; 600403; 600445; 600481; 600525; 600564; 600600; 605918; 605964; 606886; 607077; 607891; 608058; 608061; 608612; 613123; 614776.		
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For additional information, please visit the FDA Website for [Z-800](#), [Z-800WF](#), [Z-800W](#), [Z-800F](#).