

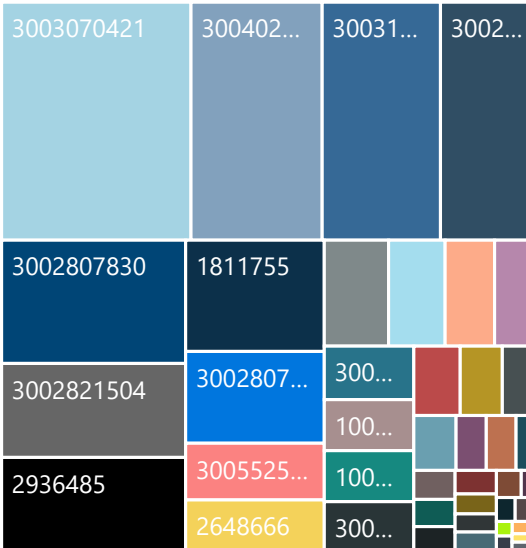
Product Registrations

| k_number | proprietary_name |
|----------|---|
| K082010 | ZYPHR DISPOSABLE CRANIAL PERFORATOR |
| K993583 | Zurich Titanium Ossicular Replacement System,add name |
| K984305 | ZETA NAIL SYSTEM |
| K982873 | ZETA LOCKING NAIL |
| | Y-Wire2 Y-Wire Guidewire |
| K060979 | XIA VITALLIUM, MULTIPLE |
| K031893 | Xia Titanium Spinal System,Xia Stainless Steel Spinal System |
| K061854 | XIA Ti LONG ARM LAM. HOOKS, MULTIPL,XIA Ti LONG ARM POLYAXIAL SCREWS,XIA Ti LC PEDICLE HOOK, SMALL,XIA Ti LONG ARM MONOAXIAL SCREWS |
| K053115 | XIA Ti AND SS SPINAL SYSTEMS |
| K060361 | XIA Ti AND SS SPINAL SYSTEMS |
| K080928 | Xia Stainless Steel,Xia |
| K012870 | Xia Stainless Steel Spinal System |
| K031090 | Xia Stainless Steel Spinal System |
| K051973 | Xia Stainless Steel Spinal System |
| K063428 | XIA SS LONG ARM POLYAXIAL SCREWS,XIA SS LONG ARM MONOAXIAL SCREWS,XIA SS L HOOKS, MULTIPLE |
| K001653 | Xia Spine System Sacral Block Assy. |
| K001272 | Xia Spine System |
| K001319 | Xia Spinal System |
| K002505 | Xia Spinal System |
| K002858 | Xia Spinal System |
| K012027 | Xia Spinal System |
| K013688 | Xia Spinal System |
| K013823 | Xia Spinal System |
| K022160 | Xia Spinal System |
| K043473 | Xia Spinal System |
| K052181 | Xia Spinal System |
| K984251 | Xia Spinal System |
| K992792 | Xia Spinal System |
| K092605 | Xia 4.5 Spinal System - Line Ext. |
| | Xia 4.5 Spinal System |
| K050461 | Xia 4.5 Spinal System |
| K052761 | Xia 4.5 Spinal System |
| K060748 | Xia 4.5 Spinal System |
| K121242 | Xia 4.5 Spinal System |

Product Code Search

Search 

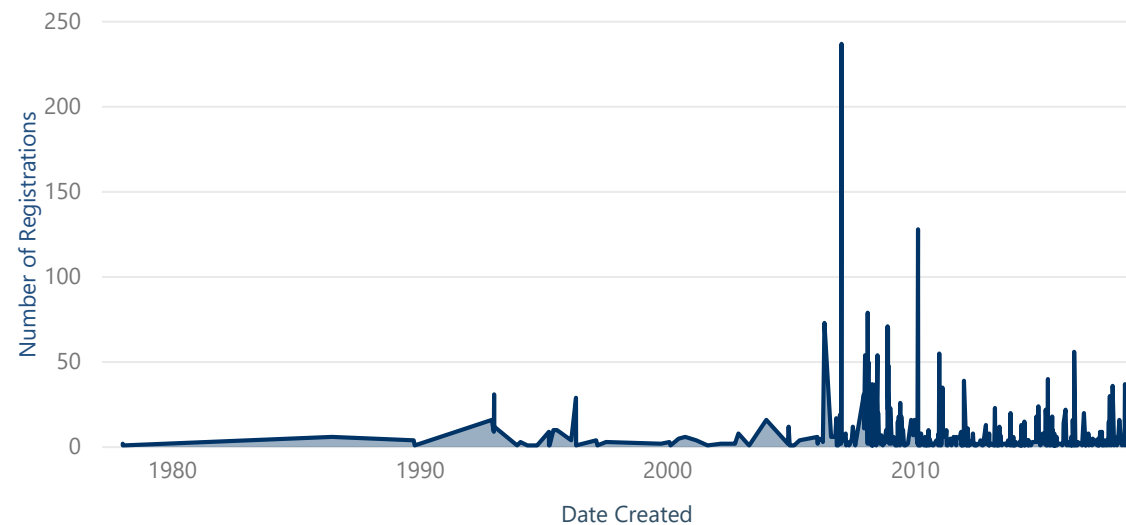
FEI Number



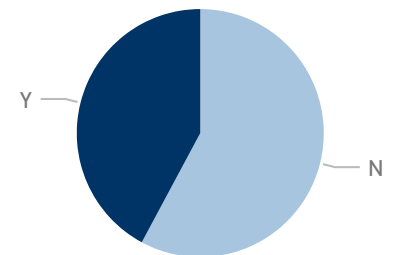
Product Code



Product Registrations by Date



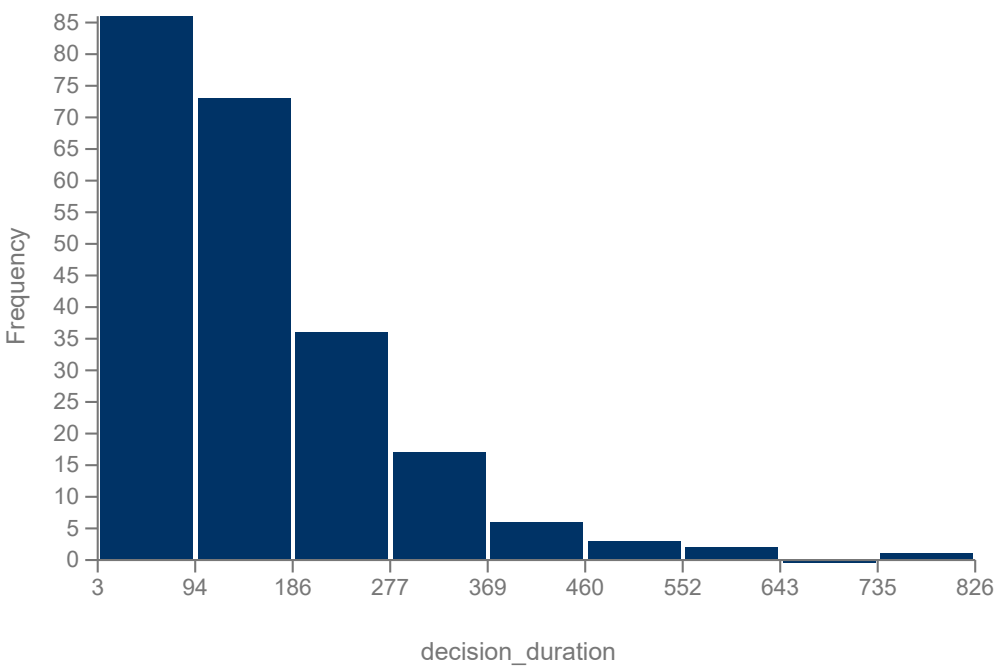
Initial Importer



510(k) Registrations

| k_number | device_name |
|----------|---|
| K820416 | #505 PORT. VITAL FUNCTIONS NEONATAL MON |
| K820417 | #506 PORT. VITAL FUNCTIONS NEONATAL MON |
| K110610 | 1.5 GE 6-CHANNEL PHASED ARRAY FLEX COIL, 3.0 GE 6-CHANNEL PHASED ARRAY FL |
| K123681 | 1.5T 4CH LARGE FLEX COIL, 1.5 4CH SMALL FLEX COIL |
| K123327 | 1.5T GEM RT OPEN ARRAY |
| K012200 | 1.5T INFINITY TWINSPEED MR SYSTEM |
| K103238 | 1.5T OPTIMA MR430S |
| K121676 | 1.5T SIGNA HDXT 3.0T SIGNA HDXT SIGNA VIBRANT |
| K060307 | 12 RL ALGORITHM |
| K060833 | 12SL ECG ANALYSIS PROGRAM |
| K092369 | 12SL ECG ANALYSIS PROGRAM |
| K141963 | 12SL ECG ANALYSIS PROGRAM |
| K864136 | 260SL IMAGING SYSTEM SMALL PARTS PROBES |
| K864135 | 280SL IMAGING SYSTEM SMALL PARTS PROBES |
| K864151 | 280SL IMAGING SYSTEM TRANVAGINAL PROBES |
| K003613 | 3.0.T SIGNA VH/I (T/R) BODY IMAGING COIL |
| K093348 | 3.0T 16 CHANNEL HEAD NECK SPINE COIL |
| K143389 | 3.0T GEM RT Open Array |
| K990550 | 3.0T SIGNA VH/I MAGNETIC RESONANCE SYSTEM |
| K030495 | 3.0T TORSO PHASED ARRAY COIL |
| K092925 | 3D ASL |
| K163205 | 48CH Head Coil |
| K180666 | 48CH Head Coil |
| K131118 | 4D VIEW |
| K101166 | 4D-VIEW 9.1 (4D VIEW PC SOFTWARE) MODEL: H48651SZ |
| K861861 | 515A NEO-TRAK NEONATAL MONITOR |
| K861931 | 645OB SECTOR/LINEAR ULTRASOUND SCANNER |
| K141093 | 6VT-D ULTRASOUND TRANSDUCER |
| K022669 | 8 CHANNEL CARDIAC PHASED ARRAY COIL |
| K032045 | 8 CHANNEL CARDIAC PHASED ARRAY COIL |
| K101492 | 8 CHANNEL CARDIAC PHASED ARRAY COIL |
| K861538 | 860 COLOR DOPPLER OR COLORVIEW 860 |
| K061953 | 9900 PLUS MOBILE FLUOROSCOPY SYSTEM WITH 3D AND NAVIGATION OPTIONS |
| K980322 | ACCENT 16, ACCENT 22 |
| K103633 | ACHILLES |

510(k) Decision Durations (days)



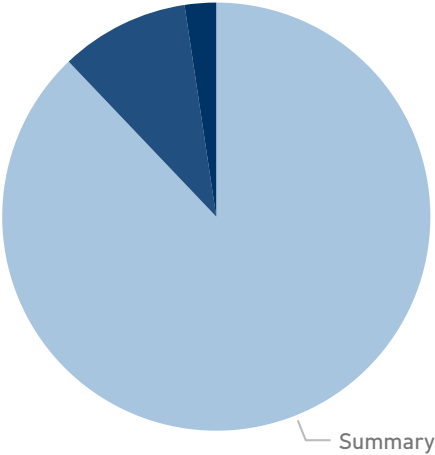
K Number Search

Average Decision Duration (days)

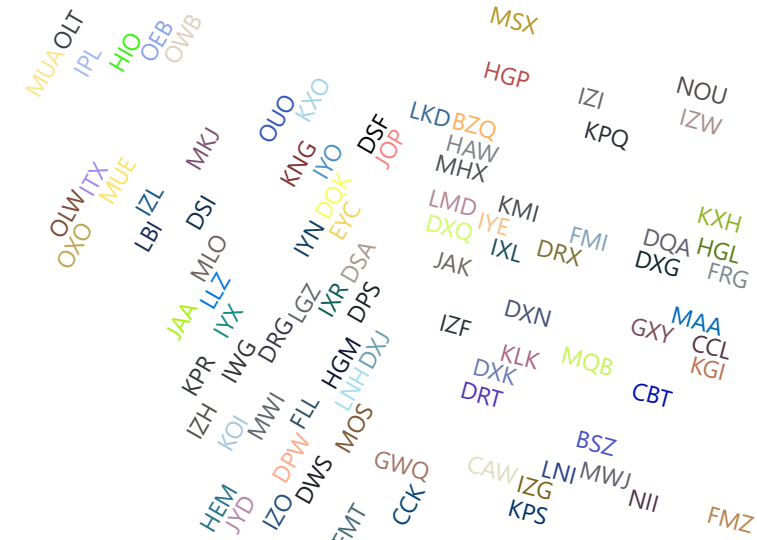
87.60

Product Code Search

Statement or Summary



Product Codes



[illegible]

| Complaint Type | Number of Complaints (Approx.) |
|--------------------|--------------------------------|
| Malfunction | 3,200 |
| Injury | 1,200 |
| Other | 600 |
| Death | 100 |
| No answer provided | 100 |

The graph illustrates the trend of adverse events (AEs) over time. The y-axis represents the 'Count of AEs' ranging from 0 to 800 in increments of 200. The x-axis represents the 'Year' from 1995 to 2018, with major ticks every 5 years. The data shows a period of low activity until around 2001, followed by a steady increase to a peak of approximately 700 AEs in 2008. This is followed by a sharp drop to about 120 AEs in 2010, a subsequent rise to a second peak of approximately 620 AEs in 2015, and a final decline to around 100 AEs by 2018.

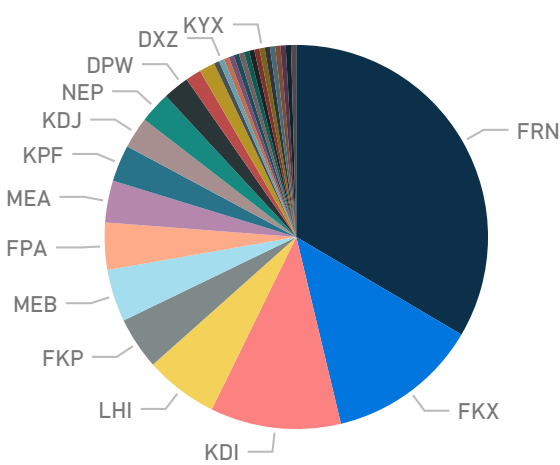
| Year | Count of AEs (Approximate) |
|------|----------------------------|
| 1995 | 0 |
| 2000 | 0 |
| 2001 | 10 |
| 2002 | 20 |
| 2003 | 120 |
| 2004 | 150 |
| 2005 | 180 |
| 2006 | 220 |
| 2007 | 350 |
| 2008 | 700 |
| 2009 | 600 |
| 2010 | 120 |
| 2011 | 120 |
| 2012 | 140 |
| 2013 | 100 |
| 2014 | 160 |
| 2015 | 620 |
| 2016 | 400 |
| 2017 | 180 |
| 2018 | 100 |

| brand_name |
|---------------------------------|
| YANKER SUCTION DEVICE |
| YANKAUER TAPERED BULBOUS TIP |
| YANKAUER SUCTION TIP |
| YANKAUER SUCTION HANDLE |
| YANKAUER SUCTION DEVICE |
| YANKAUER HANDLE |
| YANKAUER |
| YANK SUCT HNDL ONLY 50/CS |
| Y CONNECTOR SET 3 WAY |
| WOUND DRAIN |
| WHITE PROCEDURE MASK |
| WATER TRAP RAINTRAP W/CLP N/S |
| WARMER DRAPE |
| VITRECTOMY PACK (ZTAMZ)260 |
| VITAL-VUE |
| VITAL RYDER NEEDLE HOLDER, SERR |
| VITAL KNAPP IRIS SCISSORS, CVD |
| VISTEC X-RAY DETECTABLE SPONGE |
| VIASYS AVEA VENTILATOR |
| VIASYS |
| VENTED VIAL ACCESS DEVICE |
| VFI A VENTII ATOR |

Product Recalls

| product_res_number | product_description | k_numbers |
|--------------------|--|-----------|
| | ***Baxter***BUREtrol Solution Set***105" (2.7 m) 150 mL Burette***Drip Chamber Filter Valve***3 Luer Activated Valves***Male Luer Lock Adapter***with Retractable Collar***Fluid path is Sterile, Nonpyrogenic. ****Indications for Use: For the administration of fluids from a container into the patient's vascular system through a vascular access device.*** | |
| | ***Baxter***Buretrol Solution Set***105" (2.7 m)***150 mL Burette***Drip Chamber Filter Valve***3 Injection Sites Male Luer Lock Adapter with***Retractable Collar***Fluid path is Sterile, Nonpyrogenic***Indications for Use: For the administration of fluids from a container into the patient's vascular system through a vascular access device.*** | |
| | ***Baxter***Non-DEHP***BUREtrol Solution Set 105" (2.7 m), 150 mL Burette***Drip Chamber Filter Valve 3 Luer Activated Valves***Male Luer Lock Adapter***with Retractable Collar***Fluid path is Sterile, Nonpyrogenic.***Indications for Use: For the administration of fluids from a container into the patient's vascular system through a vascular access device.*** | |
| | 0.2 Micron Filter, 50 mm Product Usage: The 0.2 Micron Filter is a bacteria and particulate filter for aqueous solutions. It attaches to a standard Baxter Pharmacy Pump Tube Set. | |
| Z-2609-2016 | 1) The HomeChoice automated peritoneal dialysis system. Dataplate located on the device is labeled in part: Baxter. 2) The HomeChoice PRO automated peritoneal dialysis system. Dataplate located on the device is labeled in part: Baxter. The HomeChoice/HomeChoice Pro Automated | K102936 |

Product Code



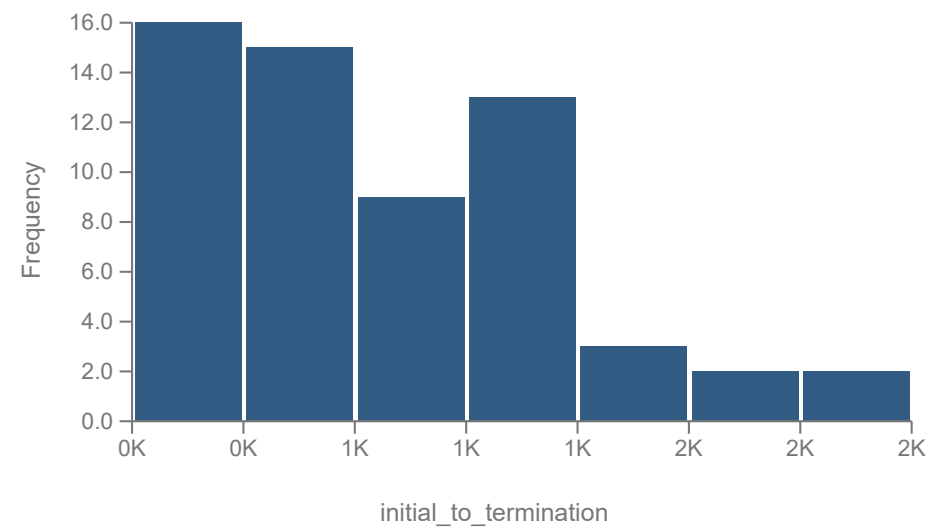
Device Classification



Status



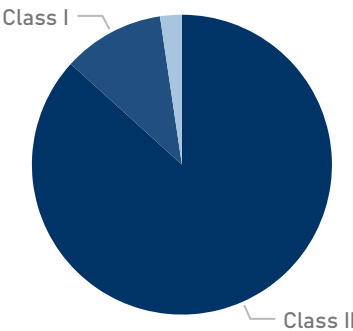
Recall Duration (days)



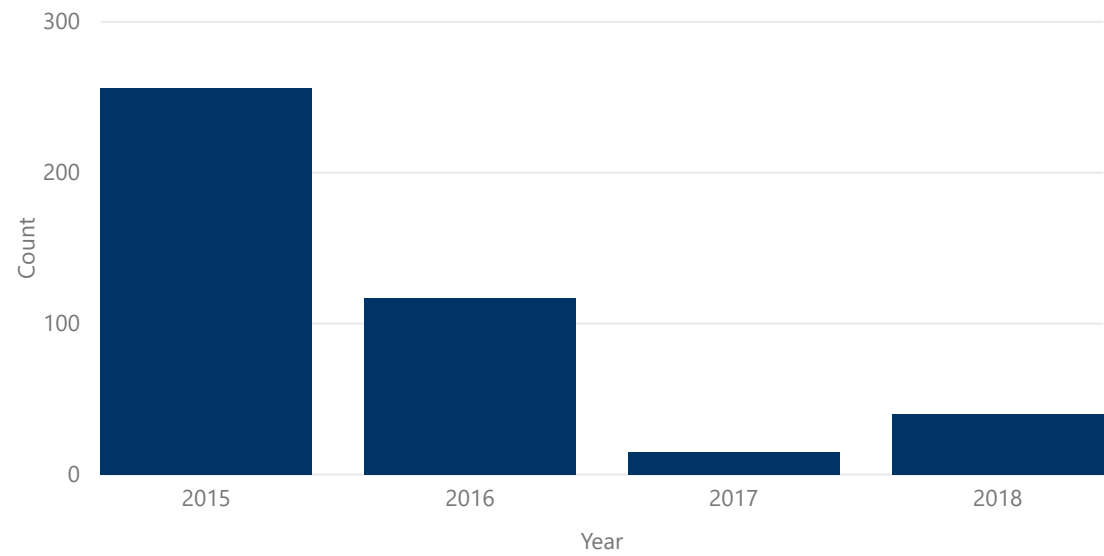
Recall Initiation Date



Recall Classification



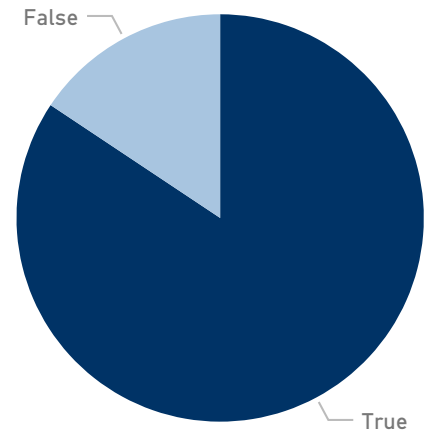
GUDID Publish Date



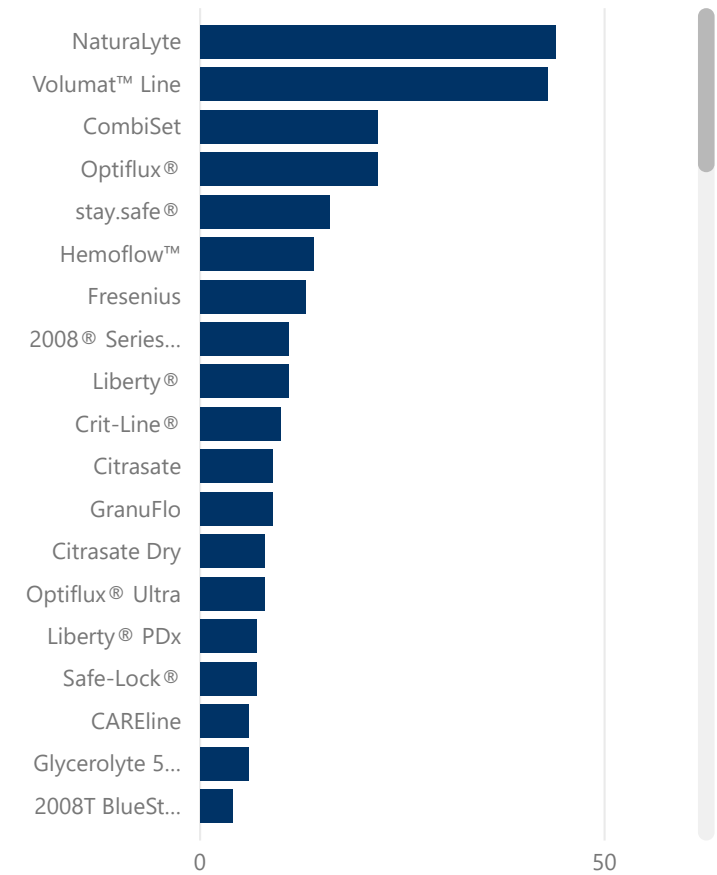
GMDN Terms

- ☐ Apheresis system
- ☐ Apheresis system tubing set
- ☐ Blood bank information system application software
- ☐ Blood collection Luer adaptor
- ☐ Blood component separator, automated
- ☐ Blood storage solution, freezing
- ☐ Blood transfer set
- ☐ Blood transfusion set
- ☐ Blood/tissue storage/culture container
- ☐ Blood-processing autotransfusion system
- ☐ Blood-processing autotransfusion system set
- ☐ Bone marrow collection/transfusion set
- ☐ Electric infusion pump administration set, single-use
- ☐ Electrical-only medical device connection cable, reusable
- ☐ Extracorporeal circuit waste bag, sterile
- ☐ General-purpose infusion pump, line-powered
- ☐ Haemodialysis concentrate
- ☐ Haemodialysis dialysate tubing

Device is single-use



Count by Brand Name



Brand Name Search

Device is a kit

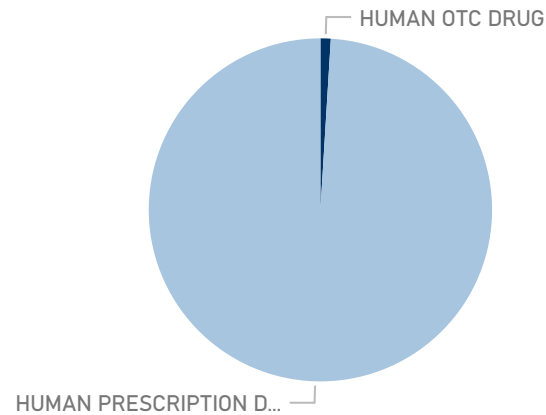


Product Codes



Drug Labels

Product Type



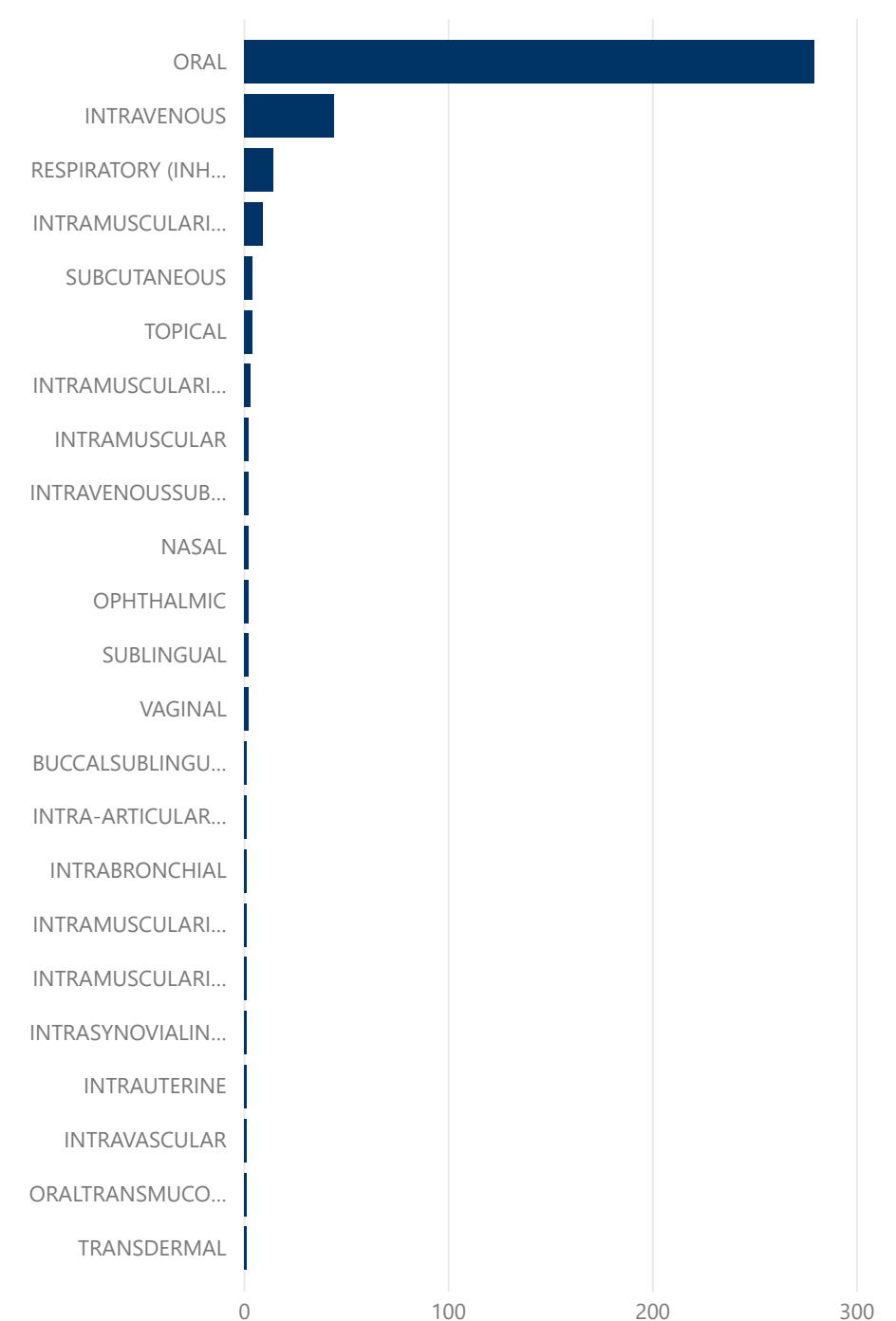
Generic Drug Name



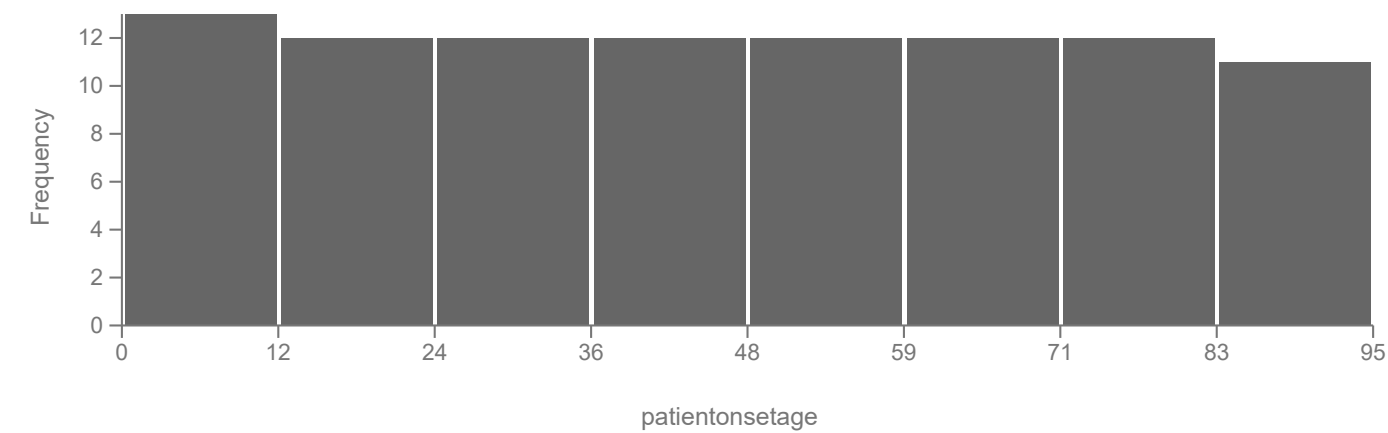
Brand Name

| openfda.brand_name |
|-------------------------------------|
| Abacavir and Lamivudine |
| Acamprosate Calcium |
| Acetaminophen and Codeine Phosphate |
| Acetazolamide |
| Acitretin |
| Acyclovir |
| Adapalene |
| Adasuve |
| Adderall |
| Adenosine |
| Adipex-P |
| Adrucil |
| Aftera |
| AirDuo RespiClick |
| AJOVY |
| Albuterol Sulfate |
| Almotriptan Malate |
| Alprostadil |

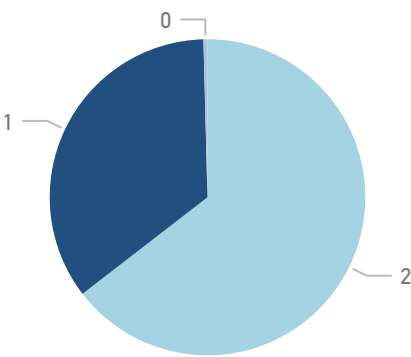
Administration Route



Patient Onset Age (years)



Patient Sex



Reaction

| reactionmeddrapt |
|--|
| Zygomycosis |
| X-ray abnormal |
| Xerophthalmia |
| Xanthopsia |
| Wrong technique in product usage process |
| Wrong patient received medication |
| Wrong drug administered |
| Wrist surgery |
| Wrist fracture |
| Wrist deformity |
| Wound secretion |
| Wound infection staphylococcal |
| Wound infection pseudomonas |
| Wound infection bacterial |
| Wound infection |
| Wound dehiscence |
| Wound complication |

Drug

| medicinalproduct | activesubstancename |
|-----------------------|-----------------------------------|
| ABATACEPT | ABATACEPT |
| ACENOCOUMAROL | ACENOCOUMAROL |
| ACETAMINOPHEN. | ACETAMINOPHEN |
| ACETAZOLAMIDE. | ACETAZOLAMIDE |
| ACETYLSALICYLIC ACID | ASPIRIN |
| ACICLOVIR | ACYCLOVIR |
| ACITROM | ACENOCOUMAROL |
| ACTAVIS UK FLUOXETINE | |
| ACTEMRA | TOCILIZUMAB |
| ACTONEL | RISEDRONATE SODIUM |
| ACTRAPID | INSULIN HUMAN |
| ACYCLOVIR. | ACYCLOVIR |
| ADALIMUMAB | ADALIMUMAB |
| ADCAL-D3 | CALCIUM CARBONATE\CHOLECALCIFEROL |
| ADOPT | TACROLIMUS |
| ADVAGRAF | TACROLIMUS |

Source Country

