**MAUDE Analysis**

One approach to identify candidate devise for analysis uses information from FDA’s MAUDE (Manufacturer and User Facility Device Experience) database. Some of the information from reports is in the public section of the database. The device Product Code is a publicly available field.

FDA makes the data available for download in a variety of datasets. This analysis started with the 2018 data in the file foidev2018. This is a pipe-delimitated text file. The analysis imported the file in MS Excel. Unfortunately, there are more records in the fil than rows in an Excel workbook. The analysis used the first of approximately 1,000,000 records imported.

The step counted the frequency of each Product Code, sorted them to determine the most frequently occurring codes, and add additional information from the FDA file foiclass. Twenty-seven product codes account for 80% of the occurrences. Table 1 provides information about these product codes.

Product Code “\*” means that the report did not include a product code.

The file foiclass does not have a regulation number for every product code.

*Table 1 Most Frequently Occurring Product Codes*

| Product Code | Count | Percent | Cum Percent | Device Name | Device Class | Regulation | Implant | Life Sustaining/Supporting |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| \* | 1048543 | 50.0% | 50.0% | #N/A | #N/A | #N/A | #N/A | #N/A |
| PQF | 115333 | 5.5% | 55.5% | Sensor, Glucose, Invasive, Non-Adjunctive | 3 |  | N | N |
| OYC | 105808 | 5.0% | 60.5% | Pump, Infusion, Insulin, To Be Used With Invasive Glucose Sensor | 3 |  | N | N |
| OZO | 39770 | 1.9% | 62.4% | Automated Insulin Dosing , Threshold Suspend | 3 |  | N | N |
| QBJ | 35978 | 1.7% | 64.2% | Integrated Continuous Glucose Monitoring System, Factory Calibrated | 2 | 862.1355 | N | N |
| LZG | 32492 | 1.5% | 65.7% | Pump, Infusion, Insulin | 2 | 880.5725 | N | N |
| OZP | 30544 | 1.5% | 67.2% | Automated Insulin Dosing Device System, Single Hormonal Control | 3 |  | N | N |
| LGW | 23443 | 1.1% | 68.3% | Stimulator, Spinal-Cord, Totally Implanted For Pain Relief | 3 |  | Y | N |
| LWS | 17720 | 0.8% | 69.1% | Implantable Cardioverter Defibrillator (Non-Crt) | 3 |  | Y | Y |
| MKJ | 17132 | 0.8% | 69.9% | Automated External Defibrillators (Non-Wearable) | 3 | 870.5310 | N | N |
| FRN | 17004 | 0.8% | 70.8% | Pump, Infusion | 2 | 880.5725 | N | N |
| NBW | 16822 | 0.8% | 71.6% | System, Test, Blood Glucose, Over The Counter | 2 | 862.1345 | N | N |
| DTB | 15226 | 0.7% | 72.3% | Permanent Pacemaker Electrode | 3 | 870.3680 | Y | N |
| GDW | 14988 | 0.7% | 73.0% | Staple, Implantable | 2 | 878.4750 | Y | N |
| LWP | 14951 | 0.7% | 73.7% | Implantable Pulse Generator, Pacemaker (Non-Crt) | 3 |  | Y | Y |
| JWH | 14243 | 0.7% | 74.4% | Prosthesis, Knee, Patellofemorotibial, Semi-Constrained, Cemented, Polymer/Metal/Polymer | 2 | 888.3560 | Y | N |
| FWM | 13540 | 0.6% | 75.0% | Prosthesis, Breast, Inflatable, Internal, Saline | 3 | 878.3530 | Y | N |
| DZE | 12685 | 0.6% | 75.6% | Implant, Endosseous, Root-Form | 2 | 872.3640 | Y | N |
| DSQ | 12639 | 0.6% | 76.2% | Ventricular (Assist) Bypass | 3 |  | Y | N |
| FTL | 11886 | 0.6% | 76.8% | Mesh, Surgical, Polymeric | 2 | 878.3300 | Y | N |
| NVN | 11350 | 0.5% | 77.4% | Drug Eluting Permanent Right Ventricular (Rv) Or Right Atrial (Ra) Pacemaker Electrodes | 3 |  | Y | Y |
| MVK | 10322 | 0.5% | 77.8% | Wearable Automated External Defibrillator | 3 |  | N | Y |
| CBK | 9840 | 0.5% | 78.3% | Ventilator, Continuous, Facility Use | 2 | 868.5895 | N | Y |
| JKA | 9755 | 0.5% | 78.8% | Tubes, Vials, Systems, Serum Separators, Blood Collection | 2 | 862.1675 | N | N |
| MDS | 9201 | 0.4% | 79.2% | Sensor, Glucose, Invasive | 3 |  | N | N |
| NIK | 8361 | 0.4% | 79.6% | Defibrillator, Automatic Implantable Cardioverter, With Cardiac Resynchronization (Crt-D) | 3 |  | Y | Y |
| NVY | 8241 | 0.4% | 80.0% | Permanent Defibrillator Electrodes | 3 |  | Y | Y |

Because the data allows identification of the regulation associated with the product code, it is interesting to know the most commonly occurring regulations in the MAUDE data. Table 2 show the regulations with 10 or more occurrences.

Regulation “\*” means that foiclass did not have a regulation number for the product code.

*Table 2 Most Frequently Occurring Regulations*

| Regulation | Count | Percent | Title |
| --- | --- | --- | --- |
| \* | 241 | 11.6% |   |
| 878.4800 | 67 | 3.2% | Manual surgical instrument for general use |
| 876.1500 | 59 | 2.8% | Endoscope and accessories |
| 888.4540 | 36 | 1.7% | Orthopedic manual surgical instrument |
| 878.3300 | 22 | 1.1% | Surgical mesh |
| 872.4565 | 20 | 1.0% | Dental hand instrument |
| 876.5130 | 17 | 0.8% | Urological catheter and accessories |
| 884.4530 | 17 | 0.8% | Obstetric-gynecologic specialized manual instrument |
| 878.4200 | 16 | 0.8% | Introduction/drainage catheter and accessories |
| 878.4820 | 15 | 0.7% | Surgical instrument motors and accessories/attachments |
| 888.3030 | 14 | 0.7% | Single/multiple component metallic bone fixation appliances and accessories |
| 878.4400 | 12 | 0.6% | Electrosurgical cutting and coagulation device and accessories |
| 866.2660 | 11 | 0.5% | Microorganism differentiation and identification device |
| 876.5820 | 11 | 0.5% | Hemodialysis system and accessories |
| 876.5980 | 11 | 0.5% | Gastrointestinal tube and accessories |
| 886.4350 | 11 | 0.5% | Manual ophthalmic surgical instrument |
| 870.1250 | 10 | 0.5% | Percutaneous catheter |
| 876.5540 | 10 | 0.5% | Blood access device and accessories |
| 878.4810 | 10 | 0.5% | Laser surgical instrument for use in general and plastic surgery and in dermatology |
| 880.5725 | 10 | 0.5% | Infusion pump |