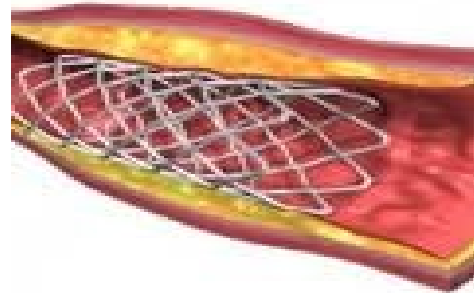
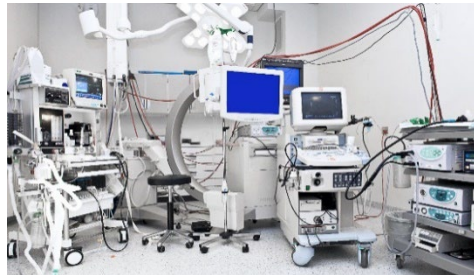
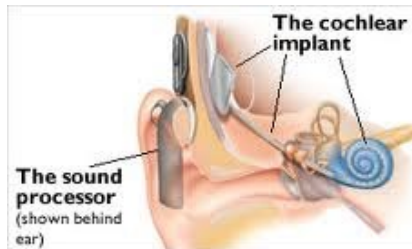
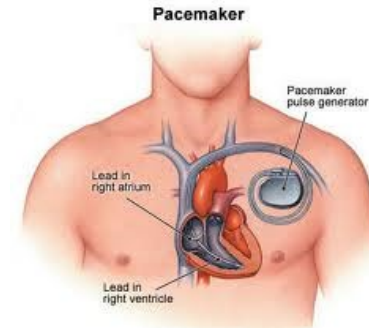


Global Medical Device Nomenclature (GMDN)

Mark Wasmuth – CEO, GMDN Agency

Why the need for the GMDN?



Consistent naming is important

Regulators / Governments need to:

- Identify the products on their national market
- Speed up Pre-market approval
- Identify trends in new equipment use
- Information on imports and exports
- Identify model and 'systematic' failure types

Healthcare Providers / Clinics need to:

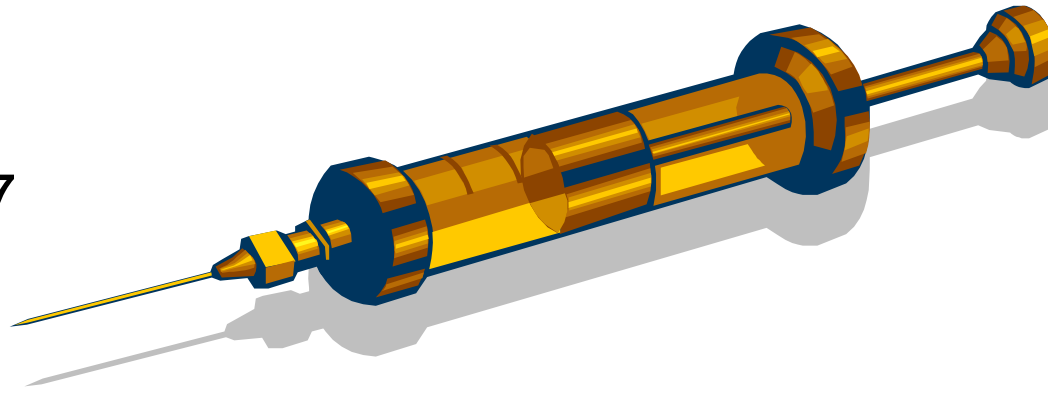
- Identify the products they want to use
- Manage their inventory more efficiently
- Identify the most effective devices

GMDN Term Structure

Each GMDN Term consists of 3 parts:

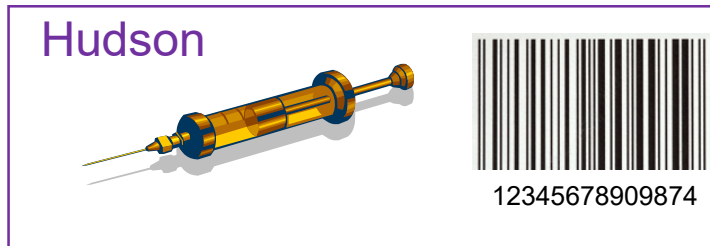
- **Term Name** General-purpose syringe, single-use
- **Definition** “A sterile device consisting of a calibrated barrel (cylinder) with plunger intended to be used for injection/withdrawal of fluids/gas (e.g., medication) to/from a medical device or the body (i.e., capable of both)...”

- **Code** 47017



UDI and GMDN work together

**Device type/model =
Unique Device Identifier**
From a single supplier
(e.g. 12345678909874)



Device Group = GMDN Term
All suppliers use same code
(e.g. GMDN Code **47017**)



What can we do with the GMDN?

Can we answer these questions with our data?

- How many products on the market?
- Who are they made by?
- What is the fastest growth by type?

- Is the fault manufacturer specific?
- What is the best device for my patient?



How many products on my market?

Explorer
Find product details by collective terms.

CT1685 Cardiac pacemakers

Active terms

Export

10 of 23,737 terms

113 of 2,270,831 products

Cardiac resynchronization therapy implantable pacemaker

Dual-chamber implantable pacemaker, demand

Dual-chamber implantable pacemaker, rate-responsive

External pacemaker, epicardial pacing

External pacemaker, transcutaneous pacing

External pacemaker, transoesophageal pacing

External pacemaker/cardioverter, epicardial pacing

Intracardiac pacemaker

Single-chamber implantable pacemaker, fixed-rate/demand

ST. JUDE MEDICAL, INC. - Accent®
ST. JUDE MEDICAL, INC. - Accent™
BOSTON SCIENTIFIC CORPORATION - ACCOLADE™ DR
BOSTON SCIENTIFIC CORPORATION - ACCOLADE™ EL DR
BOSTON SCIENTIFIC CORPORATION - ACCOLADE™ MRI DR
BOSTON SCIENTIFIC CORPORATION - ACCOLADE™ MRI EL DR
MEDTRONIC, INC. - Adapta®
MEDTRONIC, INC. - Adapta®
MEDTRONIC, INC. - Adapta®
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MEDTRONIC, INC. - Adapta® L

Explorer Find

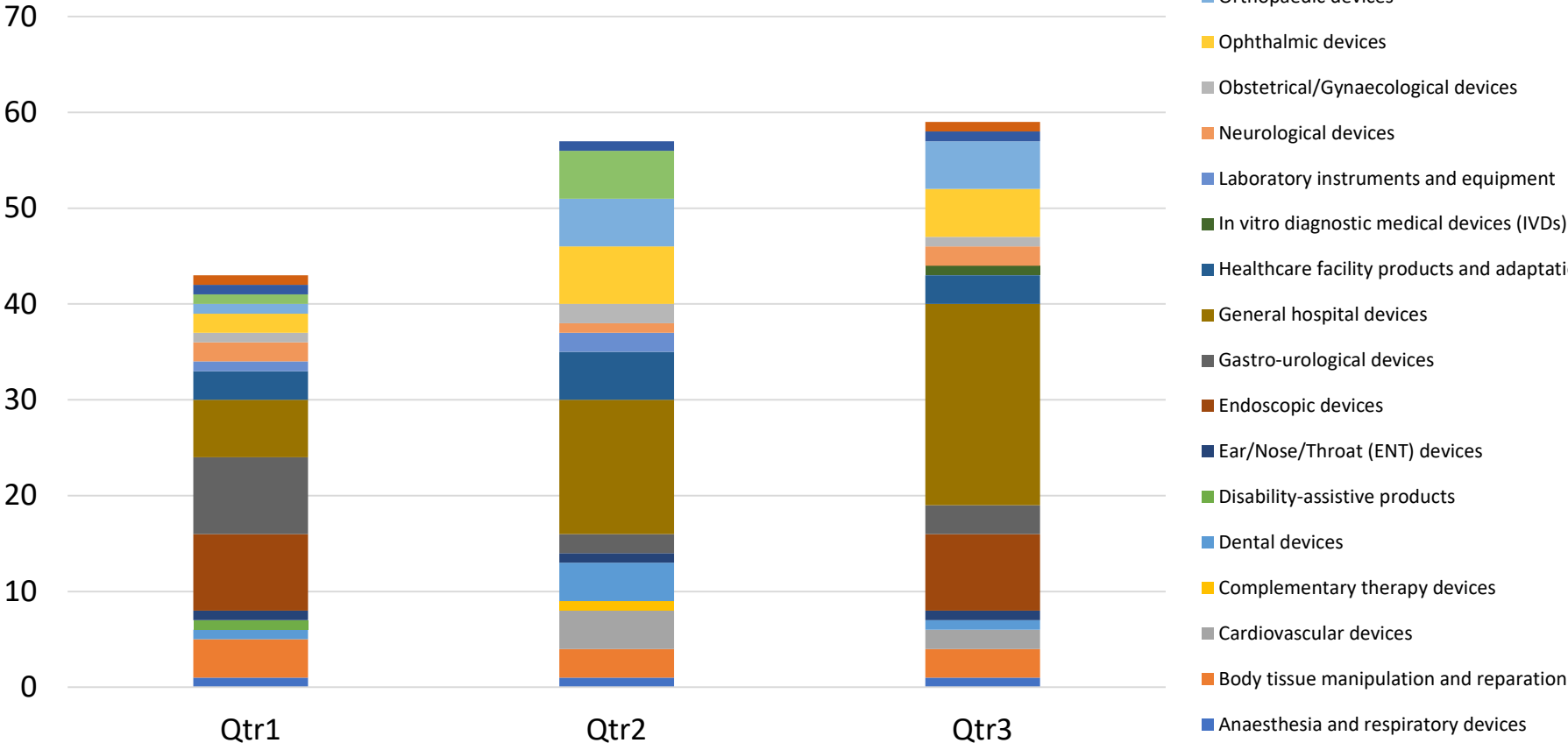
- CT2467 Cardiac ablation systems and associated devices
- CT520 Cardiac catheters and associated devices
- CT1684 Cardiac pacemakers and associated devices
 - CT1686 Cardiac pacemaker analysers/analysis systems
 - CT1685 Cardiac pacemakers**
 - CT1671 Pacing leads
- CT1640 Cardiac physiology/mapping devices
- CT1910 Cardiac resuscitators
- CT195 Cardiopulmonary bypass systems and associated devices
- CT1403 Cardiothoracic surgical procedure kits
- CT549 Cardiovascular cannulae and associated devices
- CT477 Cardiovascular catheters
- CT2510 Cardiovascular guidewires
- CT1678 Cardiovascular monitors/monitoring systems and associated devices
- CT752 Cardiovascular prosthetic devices
- CT2495 Circulatory assist devices
- CT1147 Defibrillators and associated devices
- CT953 Embolization implants and associated devices
- CT2345 Endovascular recanalization devices
- CT129 Haemodynamic measuring devices

Collective Terms ----->>>> Terms ----->>>> Unique Device

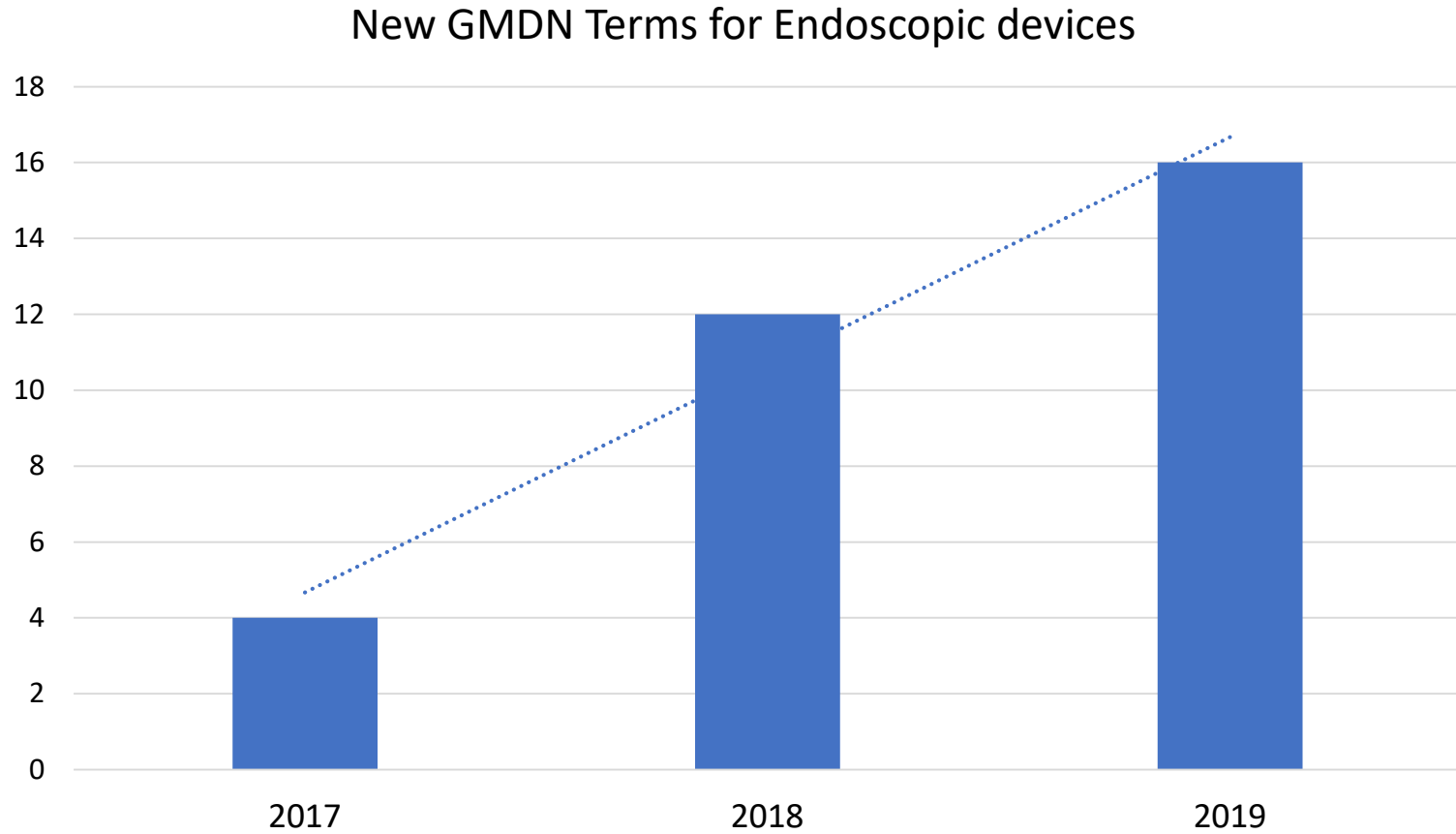
What is the trend in market growth?

Number of new GMDN Terms by Collective Term Group

(Innovation Barometer)



Maybe something of interest?

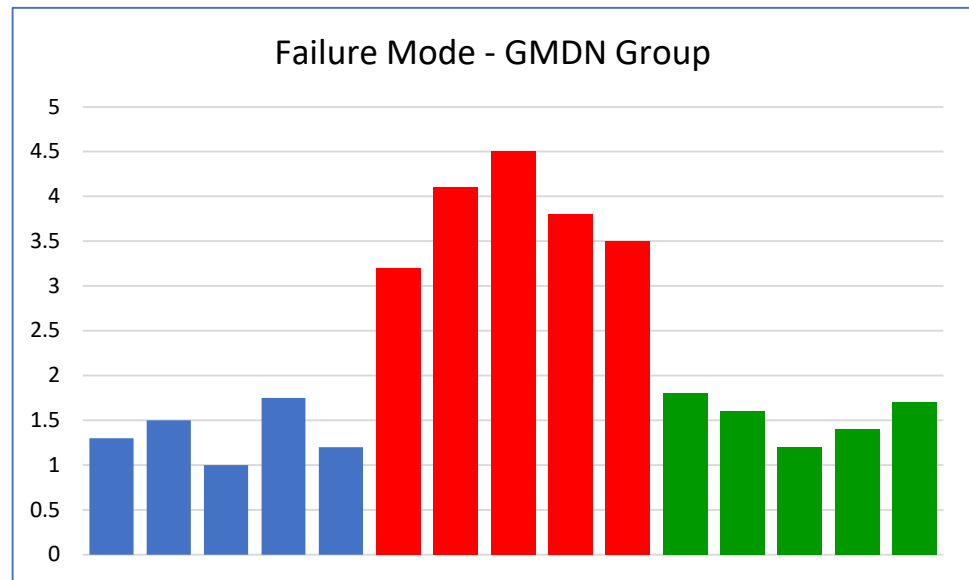


Maybe we need to invest in some endoscopy skills?

Failure Mode – by product group?

The same GMDN Code with higher failure rate

GMDN CT	GMDN Code	Manufacturer	% Failure*
1112	33719	A	1.3
1112	33719	B	1.5
1112	33719	C	1.0
1112	33719	D	1.7
1112	33719	E	1.2
1112	33694	A	3.2
1112	33694	B	4.1
1112	33694	C	4.5
1112	33694	D	3.8
1112	33694	E	3.5
1112	33181	A	1.8
1112	33181	B	1.6
1112	33181	C	1.2
1112	33181	D	1.4
1112	33181	E	1.7



Is this a design problem?

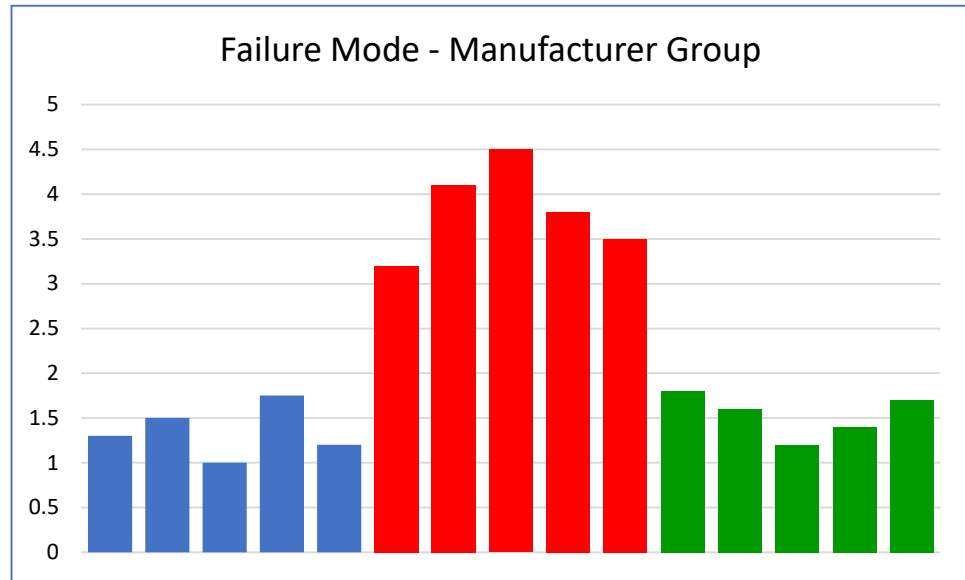
Example - **Metal-on-Metal Hip Implants**

* Simulated failure data

Failure Mode – by specific manufacturer?

The same Manufacturer with higher failure rate

GMDN Code	Make	UDI	% Failure*
36197	Jones	A	1.3
36197	Jones	A	1.5
36197	Jones	A	1.0
36197	Jones	A	1.7
36197	Jones	A	1.2
36197	Smith	B	3.2
36197	Smith	B	4.1
36197	Smith	B	4.5
36197	Smith	B	3.8
36197	Smith	B	3.5
36197	Brown	C	1.8
36197	Brown	C	1.6
36197	Brown	C	1.2
36197	Brown	C	1.4
36197	Brown	C	1.7

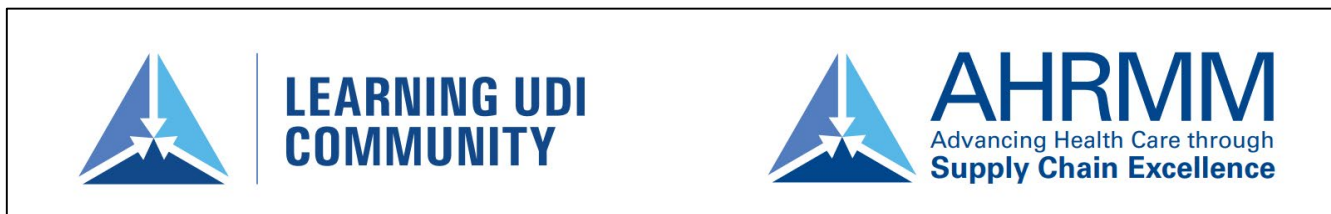


Is this a production problem?

Example – **PIP Implants**

* Simulated failure data

Clinical evaluation of GMDN?



High-Risk Implants Work Group Report:

“Use of the GMDN term assigned to UDI-DIs and their associated implantable collective codes supports the most accurate programmable approach to identifying implantable devices.”

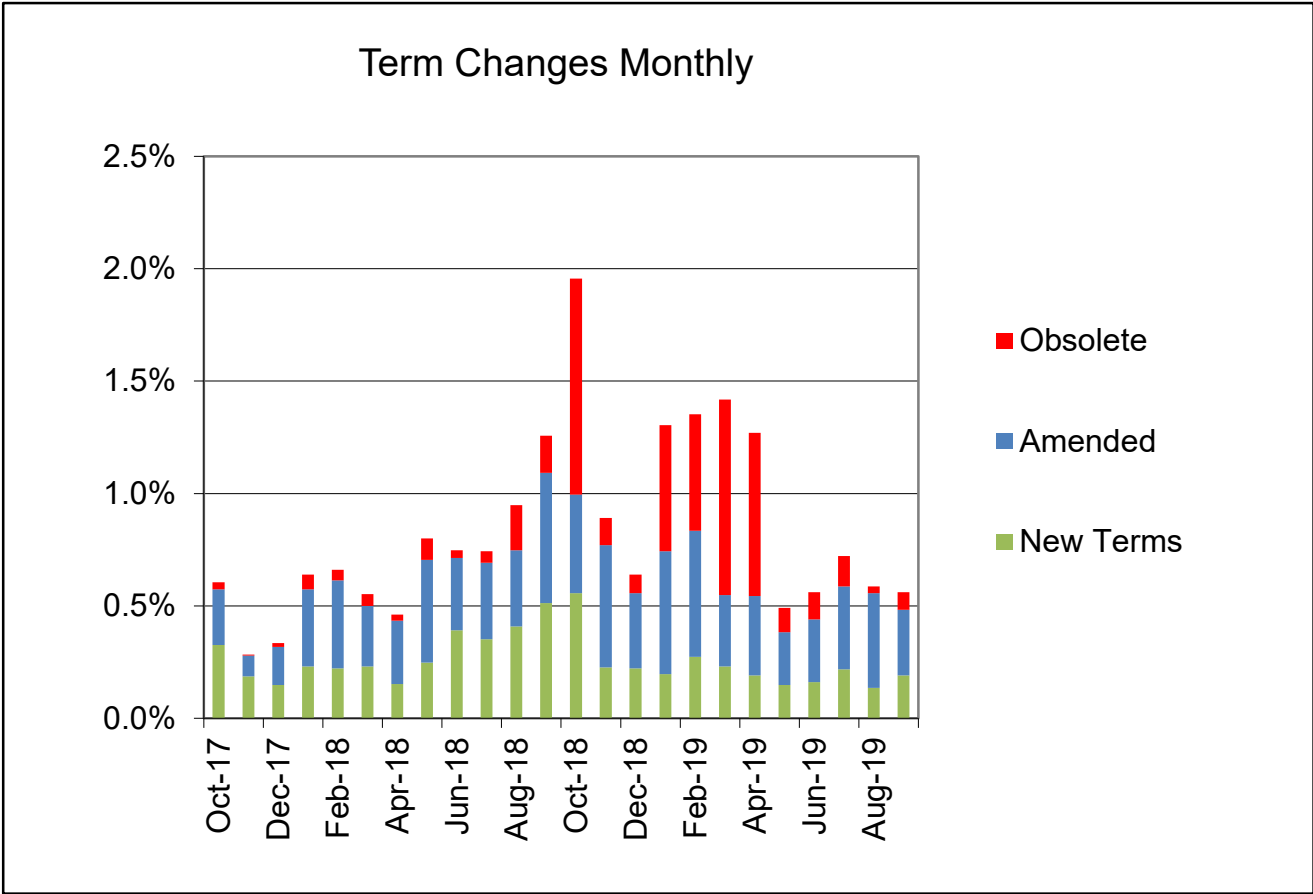
More at www.ahrmm.org/LUC

What else can we identify?

Identifying products that have similar attributes allows us to:

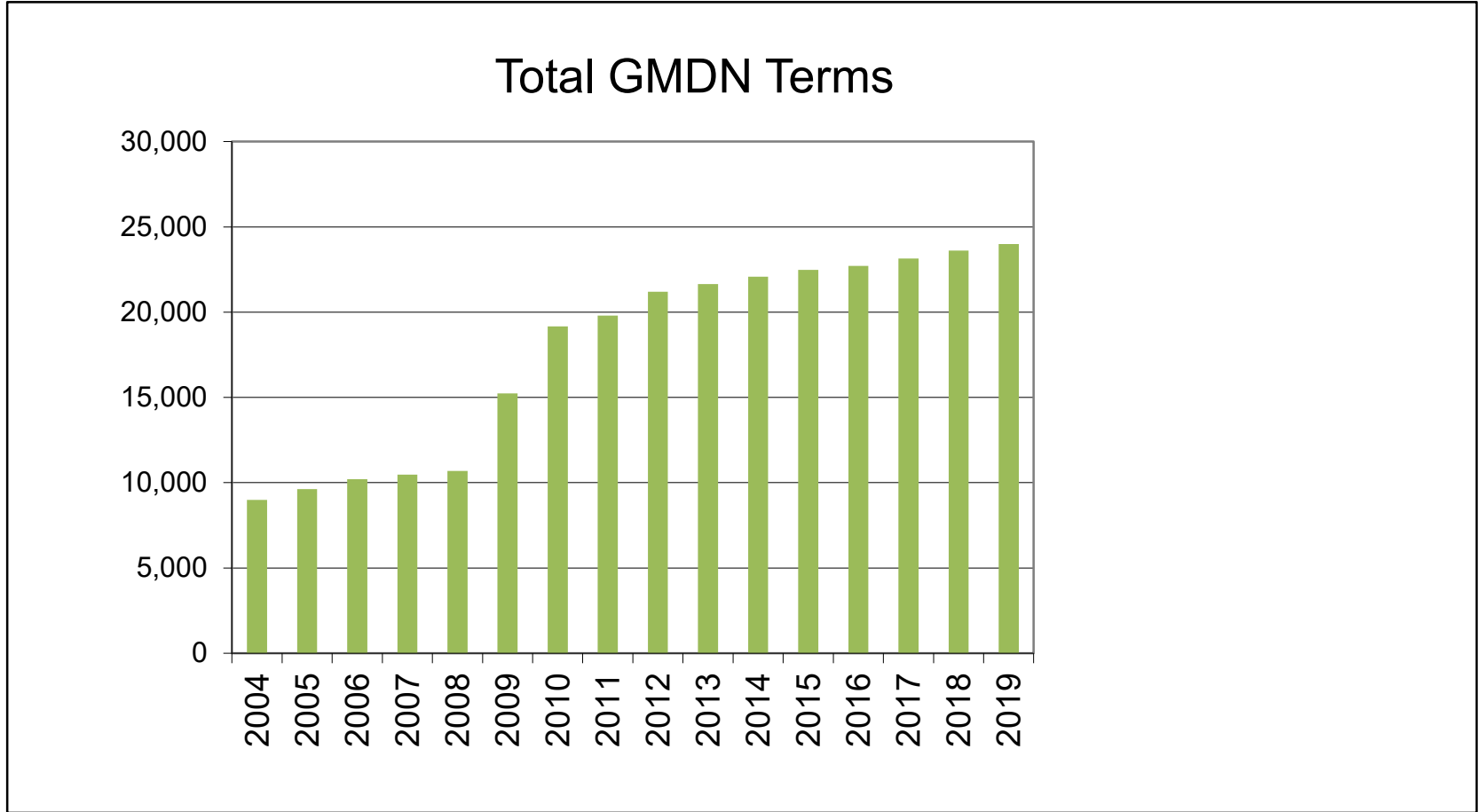
- Identify 'high risk in use' devices
- Products that have specific training needs
- Identify any hazardous materials
- Any services needed, such as electricity or compressed air
- Maintenance & calibration requirements
- Product containing software
- Contaminated waste management
- Etc, etc, etc.....

What is the Trend for GMDN changes?



“Our sector files one new European patent every 50 minutes” - MedTechEurope

New Terms are increasing, but slowly



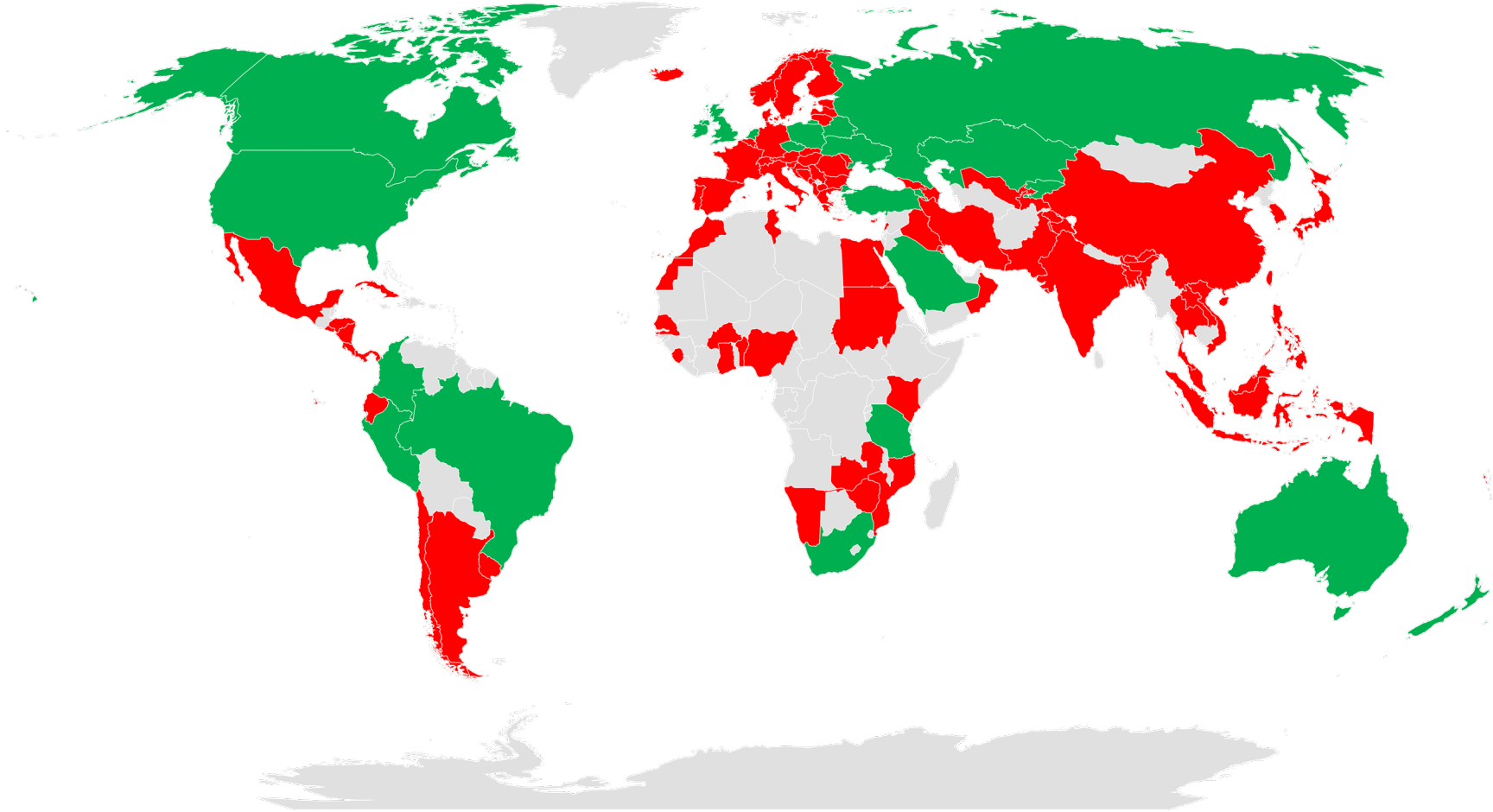
The GMDN today

- Used by 110 national Medical Device Regulators
- Has over 6500 Manufacturers registered today
- Up-to-date with latest medical technology
- 24,000 product descriptions with detailed definitions
- Translated into 24 languages

The GMDN is available now!

Global use of GMDN

- Member
- Regulated



Who is the GMDN Agency?

- UK Registered Charity since 2013
- Set-up by medical device Regulators
- Funded by Members, who benefit from global compliance
- Governance:
 - Board of volunteer Trustees
 - Policy Advisory Group
 - Regulators
 - Healthcare Providers
 - Manufacturers

Join us at www.gmdnagency.org

It's all about sharing information!

