各国不良事件查询方式

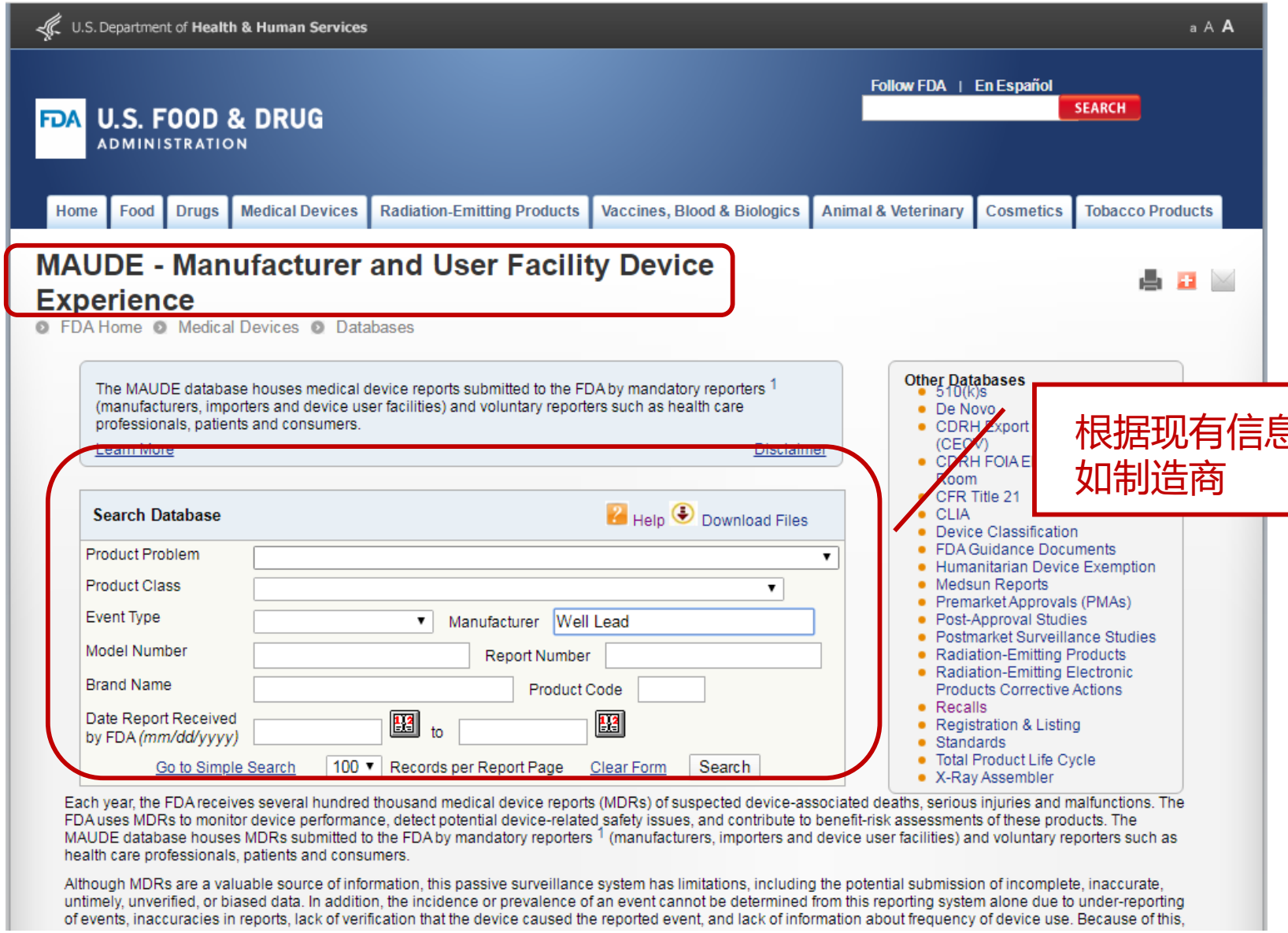
1、美国 FDA
2、澳大利亚 TGA
3、加拿大
4、英国 MHRA
5、日本 PMDA
6、中国
7、德国 BfArM

一、FDA

- 网站：https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/search.cfm

打开网页即是以下界面

① 不良事件

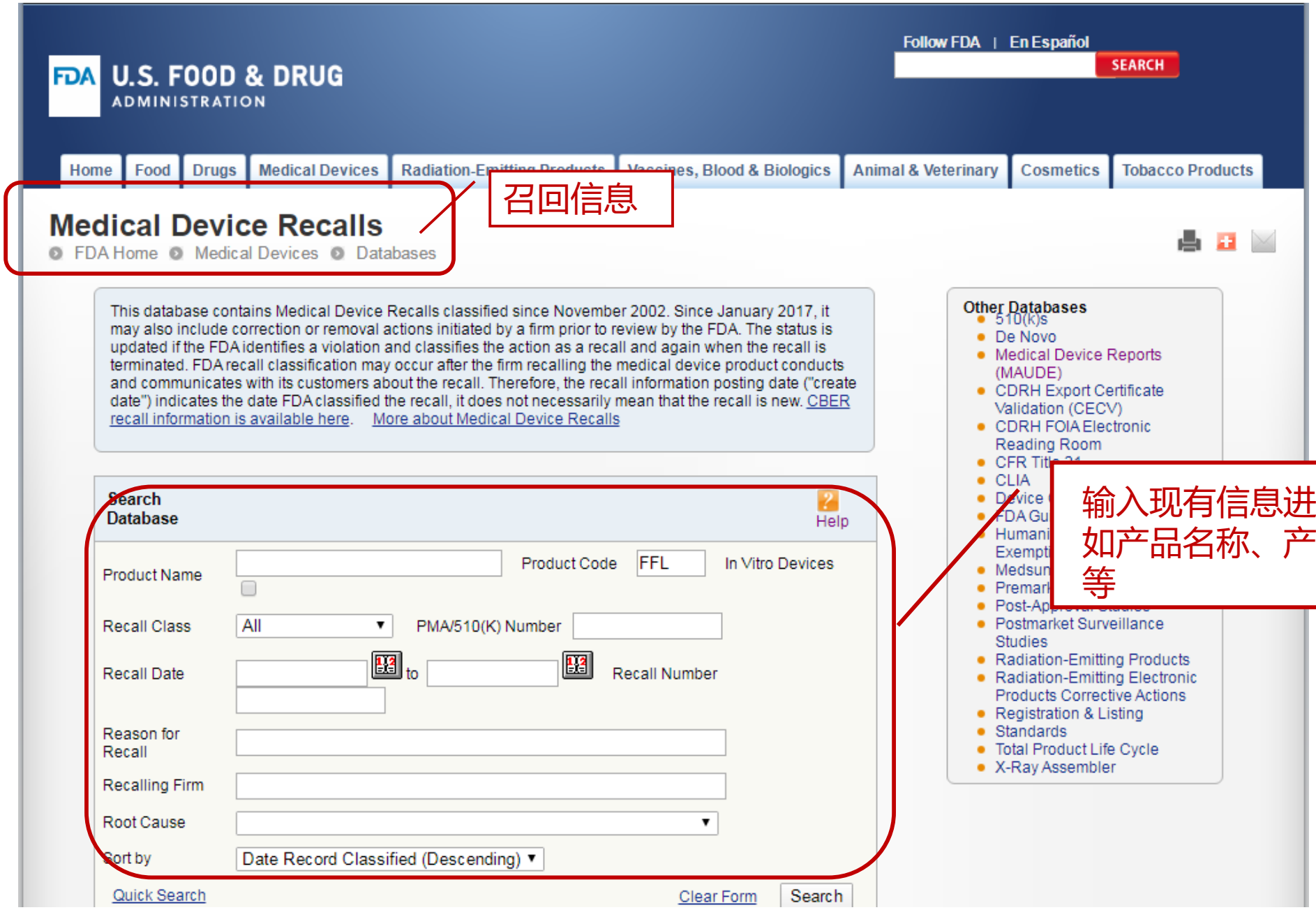


根据现有信息查询。如制造商

① 不良事件


U.S. Department of Health & Human Services
U.S. FOOD & DRUG ADMINISTRATION
Follow FDA | En Español
SEARCH
Home | Food | Drugs | Medical Devices | Radiation-Emitting Products | Vaccines, Blood & Biologics | Animal & Veterinary | Cosmetics | Tobacco Products
MAUDE - Manufacturer and User Facility Device Experience
FDA Home | Medical Devices | Databases
①、召回
510(k) | DeNovo | Registration & Listing | Adverse Events | Recalls | PMA | HDE | Classification | Standards
CFR Title 21 | Radiation-Emitting Products | X-Ray Assembler | Medsun Reports | CLIA | TPLC
导出清单
31 records meeting your search criteria returned- Manufacturer: Well Lead
New Search
Export to Excel | Help
查看单个事件详细信息
Manufacturer
Date Report Received
WELL LEAD SUNMED 05/07/2020
WELL LEAD SUNMED 04/30/2020
WELL LEAD SUNMED 04/30/2020
WELL LEAD MEDICAL CO. LTD CURAPLEX 36619 NPA KIT 01/04/2019
WELL LEAD MEDICAL CO. LTD CURAPLEX NASOPHARYNGEAL AIRWAY 01/04/2019
WELL LEAD SUNMED 10/02/2018
WELL LEAD SUNMED 10/02/2018
WELL LEAD SUNMED 06/12/2018
WELL LEAD MEDICAL ET TUBE W/ STYLET, CUFFED SIZE 7 09/22/2016
GUANGZHOU WELL LEAD TUBING SUCTION 9/32" 10/26/2015
WELL LEAD MEDICAL TUBE 6MM X 12 FT C&B 07/24/2015

② 召回信息



输入现有信息进行查询。如产品名称、产品code等

② 召回信息

U.S. Department of Health & Human Services

a A A

FDA U.S. FOOD & DRUG ADMINISTRATION

Follow FDA | En Español

SEARCH

Home | Food | Drugs | Medical Devices | Radiation-Emitting Products | Vaccines, Blood & Biologics | Animal & Veterinary | Cosmetics | Tobacco Products

Medical Device Recalls

FDA Home › Medical Devices › Databases

1 to 7 of 7 Results

Product Code: *FFL*

Results per Page

导出清单

New Search | Export To Excel | Help

Product Description	Recall Class	FDA Recall Posting Date	Recalling Firm
Bard Dimension Stone Basket Product Usage: The Bard Dimension Stone Basket Is A Teardrop-Shaped ...	2	10/31/2014	C.R. Bard, Inc.
Stone Retrieval Basket Model #: BOS390-105 Used To Entrap And Remove Renal Stones And Calculi Via ...	2	01/13/2009	Sterilmed Inc
Boston Scientific Brand Zero Tip Nitinol Stone Retrieval Basket, 12 Mm, 90 Cm, 1.9 Fr., Sterile, Lat...	2	02/08/2006	Boston Scientific Corp
Boston Scientific Brand Zero Tip Nitinol Stone Retrieval Basket, 12 Mm, 120 Cm, 1.9 Fr., Sterile, La...	2	02/08/2006	Boston Scientific Corp
V. Mueller Pfister-Schwartz Stone Retriever 4-Wire Basket, Without Filiform Tip; A Sterile, Single U...	2	11/05/2004	Cardinal Health
Bard® Dimension® Stone Basket, Rx Only, Sterile, C.R.Bard, Inc., Covington, GA 30014	2	01/09/2004	C.R. Bard, Inc., Urological Division
Bard® Platinum Class® II Flat Wire Stone Basket, Ureteral Stone Dislodger, Rx Only, Sterile, C.R.Bar...	2	01/09/2004	C.R. Bard, Inc., Urological Division

Page Last Updated: 01/22/2021

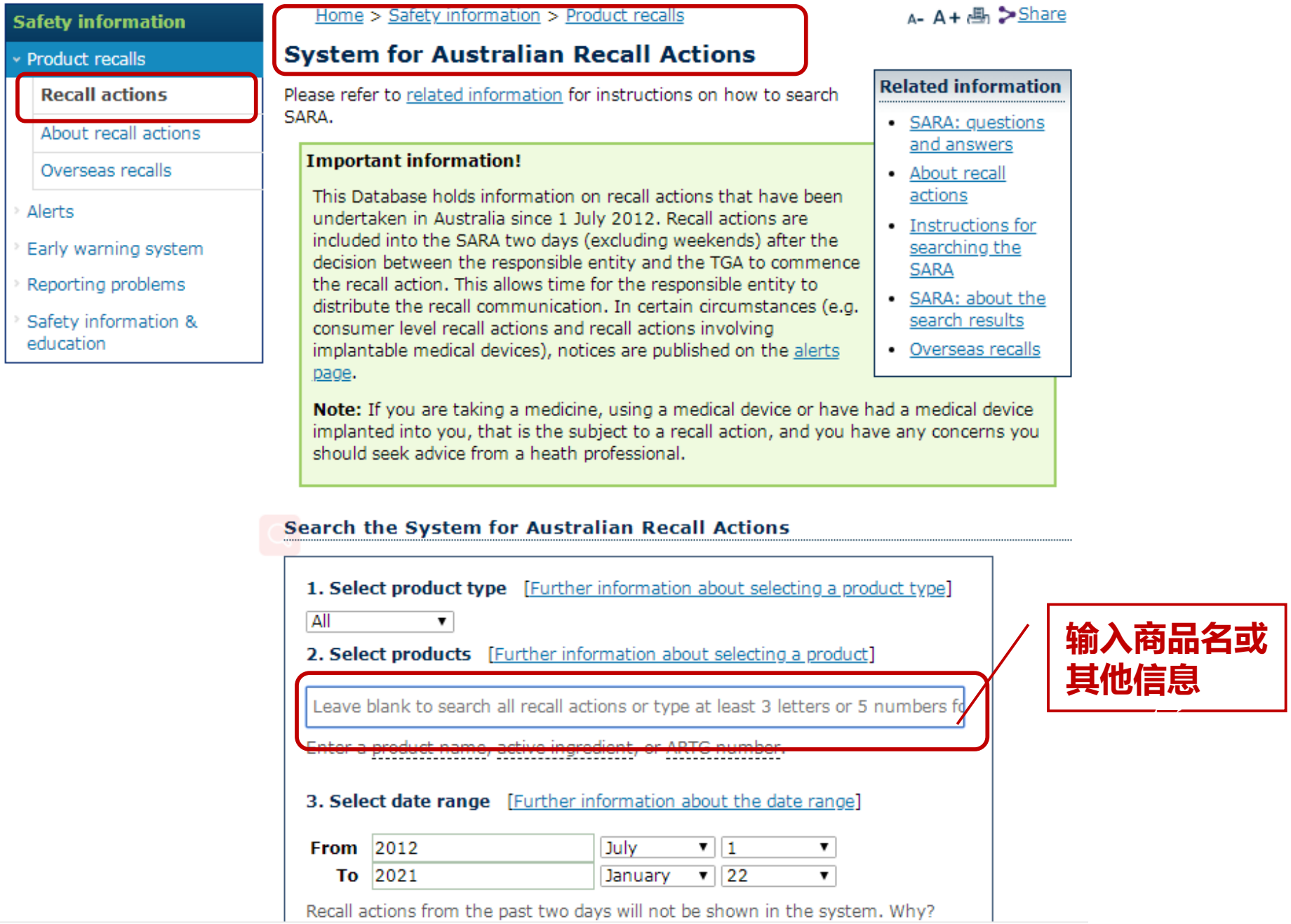
Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.

Language Assistance Available: Español | 繁體中文 | Tiếng Việt | 한국어 | Tagalog | Русский | العربية | Kreyòl Ayisyen | Français | Polski | Português | Italiano | Deutsch | 日本語 | فارسی | English

二、澳大利亚

- 网站：https://apps.tga.gov.au/Prod/sara/arn-entry.aspx

① 召回信息


Safety information
Product recalls
Recall actions
About recall actions
Overseas recalls
Alerts
Early warning system
Reporting problems
Safety information & education
Home > Safety information > Product recalls
A- A+ Share
System for Australian Recall Actions
Please refer to related information for instructions on how to search SARA.
Related information
SARA: questions and answers
About recall actions
Instructions for searching the SARA
SARA: about the search results
Overseas recalls
Important information!
This Database holds information on recall actions that have been undertaken in Australia since 1 July 2012. Recall actions are included into the SARA two days (excluding weekends) after the decision between the responsible entity and the TGA to commence the recall action. This allows time for the responsible entity to distribute the recall communication. In certain circumstances (e.g. consumer level recall actions and recall actions involving implantable medical devices), notices are published on the alerts page.
Note: If you are taking a medicine, using a medical device or have had a medical device implanted into you, that is the subject to a recall action, and you have any concerns you should seek advice from a heath professional.
Search the System for Australian Recall Actions
1. Select product type [Further information about selecting a product type]
All
2. Select products [Further information about selecting a product]
Leave blank to search all recall actions or type at least 3 letters or 5 numbers fo
Enter a product name, active ingredient, or ARTG number.
3. Select date range [Further information about the date range]
From 2012 July 1
To 2021 January 22
Recall actions from the past two days will not be shown in the system. Why?
输入商品名或其他信息

② 不良事件数据库

Australian Government
Department of Health
Therapeutic Goods Administration

Search TGA

Home | Safety information | Consumers | Health professionals | Industry | About the TGA | News room

Safety information

- Report a problem or side effect
- Alerts
- Recalls
- Prescription opioids
- Medicine shortages
- Early warning system
- Black Triangle Scheme
- Safety information & education
  - Medicines safety
  - Medical devices safety
  - Database of Adverse Event Notifications (DAEN)
- COVID-19 vaccines

Home » Safety information » Safety information & education

A- A+ Share

Database of Adverse Event Notifications (DAEN)

30 October 2018

The Therapeutic Goods Administration (TGA) receives adverse event reports associated with medicines and medical devices. These reports come from a wide range of sources, including members of the public, general practitioners, nurses, other health professionals and the therapeutic goods industry.

There are two search facilities below:

- **DAEN - medicines** provides information about adverse events related to **medicines and vaccines** used in Australia.
- **DAEN - medical devices** provides information about adverse events related to **medical devices** used in Australia.

DAEN - medicines

The Database of Adverse Event Notifications - medicines contains information from reports of adverse events that the TGA has received in relation to medicines, including vaccines, used in Australia.

Search DAEN - medicines

More information about DAEN - medicines

- Consumer questions and answers: DAEN - medicines
  Consumer questions and answers about the DAEN -

DAEN - medical devices

The Database of Adverse Event Notifications - medical devices contains information from reports of adverse events that the TGA has received in relation to medical devices used in Australia.

Search DAEN - medical devices

More information about DAEN - medical devices

- Consumer questions and answers: DAEN - medical

1、安全信息

2、不良事件

3、医疗器械

More about the database

Search the DAEN - medical devices

You must select one or more medical devices and a date range.

1. Select medical devices [Further information about selecting a medical device]

Well Lead

Searching, please wait...

Devices found for 'Well...'
None selected

- Medline Assembly Australia Pty Ltd - Medline Haemostat Medline Haemostat Spencer **Well**s 20cm Straight - Surgical procedure kit, obstetrical/gynaecological, single-use, medicated *(Surgical procedure kit, obstetrical/gynaecological, single-use, medicated)*
- Medline International Two Australia Pty Ltd - **Well**ness Plus Foldable Transport Wheelchair *(Transport wheelchair, collapsible)*
- **Well** Lead Medical Co Ltd - DISP SIL REINFORCD/FLEX LMA SIZE 4 - Airway, laryngeal, single-use *(Airway, laryngeal, single-use)*
- **Well** Lead Medical Co Ltd - Pro-breathe LMA size 2 *(Airway, laryngeal, single-use)*
- **Well** Lead Medical Co Ltd - Introducer/Bougie Adult *(Tube, tracheal*

2. Select date range [Further information about the date range]

From	2012	July	1
To	2020	October	7

Reports from the last three months have not been included in the database. Why?

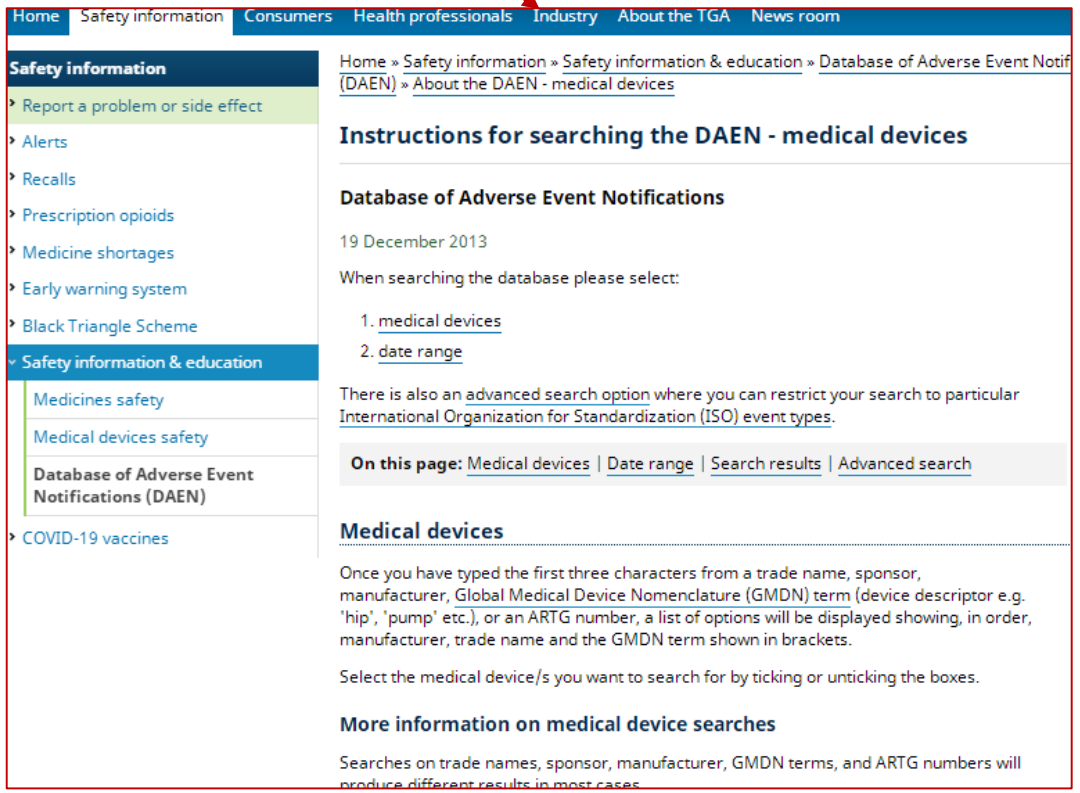
Show advanced search options [Further information about advanced search options]

Search

1、查询关键字

2、更多信息

3、单个/批量查询



Home | Safety information | Consumers | Health professionals | Industry | About the TGA | News room

Safety information
- Report a problem or side effect
- Alerts
- Recalls
- Prescription opioids
- Medicine shortages
- Early warning system
- Black Triangle Scheme
- Safety information & education
  - Medicines safety
  - Medical devices safety
  - Database of Adverse Event Notifications (DAEN)
- COVID-19 vaccines

Home » Safety information » Safety information & education » Database of Adverse Event Notif (DAEN) » About the DAEN - medical devices

Instructions for searching the DAEN - medical devices

Database of Adverse Event Notifications

19 December 2013

When searching the database please select:

1. medical devices
2. date range

There is also an advanced search option where you can restrict your search to particular International Organization for Standardization (ISO) event types.

On this page: Medical devices | Date range | Search results | Advanced search

Medical devices

Once you have typed the first three characters from a trade name, sponsor, manufacturer, Global Medical Device Nomenclature (GMDN) term (device descriptor e.g. 'hip', 'pump' etc.), or an ARTG number, a list of options will be displayed showing, in order, manufacturer, trade name and the GMDN term shown in brackets.

Select the medical device/s you want to search for by ticking or unticking the boxes.

More information on medical device searches

Searches on trade names, sponsor, manufacturer, GMDN terms, and ARTG numbers will produce different results in most cases

3、单个/批量查询

Database of Adverse Event Notifications (DAEN)

or likelihood of an adverse event occurring.

- Search the ARTG

1 medical device selected between 01/01/2018 - 07/10/2020.

Search results

The results are shown in two tabs.

Number of reports: **1**

More information on the search results

Medical device summary | List of reports

Medical device summary

Further information about the medical device summary

Information on printing search results

Sort by: Report date - earliest first

Print version of this report

导出报告

Report number	Report date	Trade name	Sponsor	Ma
52346	20/07/2018	DISP SIL REINFORCD/FLEX LMA SIZE 4 - Airway, laryngeal, single-use	Device Technologies Australia Pty Ltd	Wel Mec

Page 1 of 1 Records to display: 25

« New search | « Modify search

Important information on the Database of Adverse Event Notifications -

三、加拿大

- 网站：https://healthycanadians.gc.ca/recall-alert-rappel-avis/index-eng.php

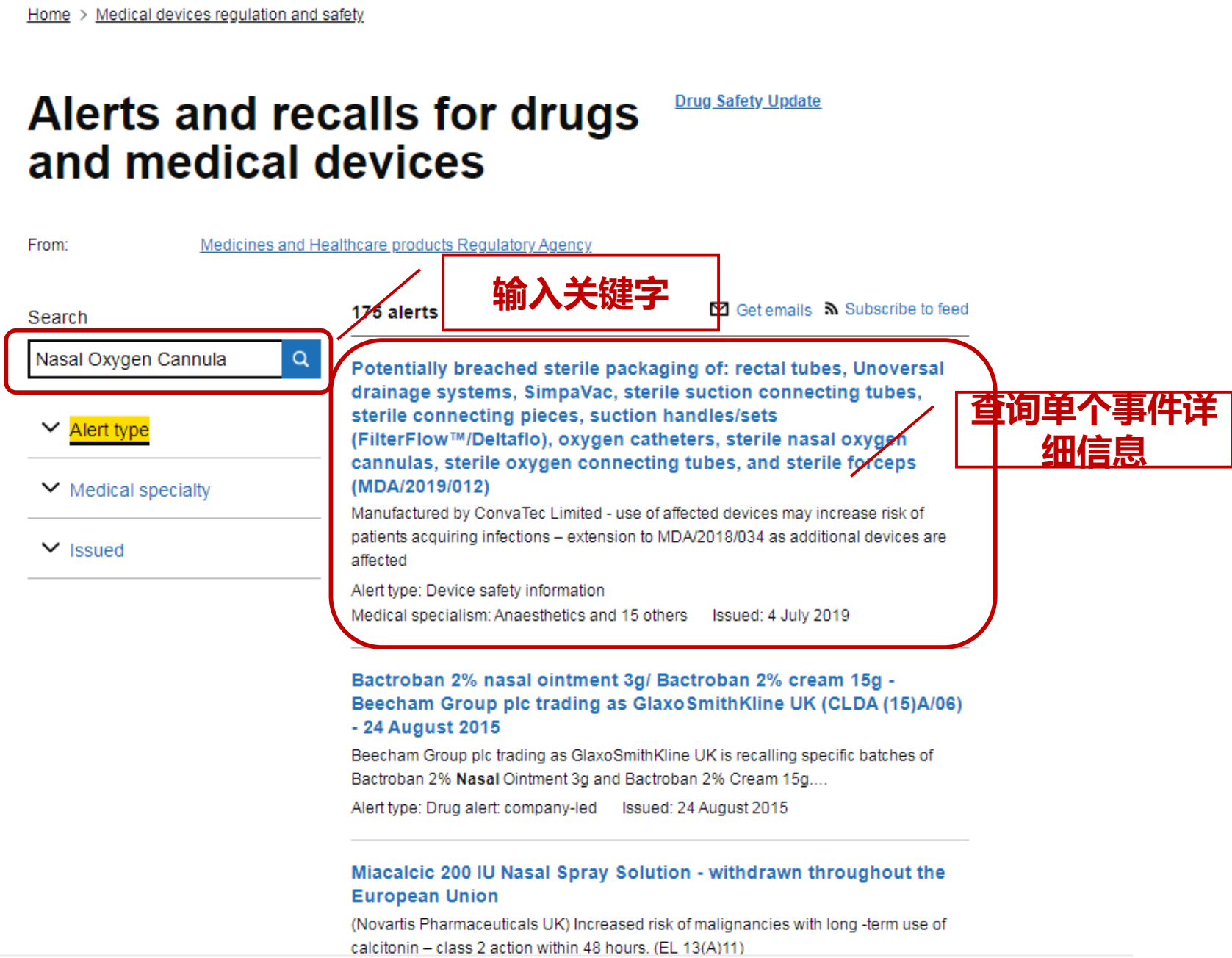

Healthy Canadians
Canada
Recalls & alerts
Kids
Food
Your Health
Environment
Consumer products
Home › Recalls & Alerts › Advanced search
Share
Contrast
Print
Advanced search
Search
Clear
Category:
All categories
Consumer products
Food
Health products
Vehicles
Advanced options
Search for:
All of these words
Ureteral Dilation Balloon Cathete
AND
Exclude
Start date (YYYY-MM-DD)
年 /月/日
End date (YYYY-MM-DD)
Type:
All types
Advisory
Recall
输入关键字


Healthy Canadians
Canada
Recalls & alerts
Kids
Food
Your Health
Environment
Consumer products
Home › Recalls & Alerts › Search results
Share
Contrast
Print
Search results
Search Alerts
Advanced search
Search terms:
Use AND, OR, NOT or " " for phrases or specific product names to improve your results.
For example, "peanuts" OR "peanut butter"
Narrow results by:
1 items found for "Ureteral Dilation Balloon Cathete"
Results per page: 10
Category:
Health products (1)
产品类型
查询事件详细信息
Results per
Various Catheter and Stent Sets from Cook's Inc (2019-01-07)
Various Catheter and Stent Sets from Cook's Inc (2019-01-07) Affected products Urethral Dilator Set Angled Tip Ureteral Catheter Set Bentson Wire Guide C-Flex Double Pigtail Ureteral Stent Set Sof-Flex Double Pigtail Ureteral Stent Set Sof-Flex Multi-Length Ureteral Stent Set Urethral Dilation...
Posted: 2019-01-07
Type of communication: Recall
事件类型
Results per page: 1-1 of 1

四、英国

- 网站：

https://www.gov.uk/drug-devic
alerts?keywords=&alert_type[]=
evices&issued_date[from]=&iss
d_date[to]



Published 28 February 2019
From: Medicines and Healthcare products Regulatory Agency

Alert type: **Device safety information**
Medical specialty: **Anaesthetics, Cardiology, Care home staff, Cosmetic surgery, Critical care, Dentistry, General practice, General surgery, Haematology and oncology, Infection prevention, Obstetrics and gynaecology, Orthopaedics, Paediatrics, Theatre practitioners, Urology, Vascular and cardiac surgery**
Issued: **4 July 2019**

Contents

— Medical Device Alert
— Summary
— Action
— Device details
— Manufacturer contacts
— Distribution

事件包含内容

Brexit

Check how the new Brexit rules affect you

Related content

Suction catheters, gastro-enteral tubes, intermittent urology catheters and sterile urine drainage bags – potential breach in sterile barrier packaging (MDA/2018/034)

Drug Alert Class 4: Paracetamol Infusion, Accord. (MDR 07-02/19)

All T34 ambulatory syringe pumps need a sponge pad fitted to the battery compartment to prevent battery connection issues (MDA/2019/013)

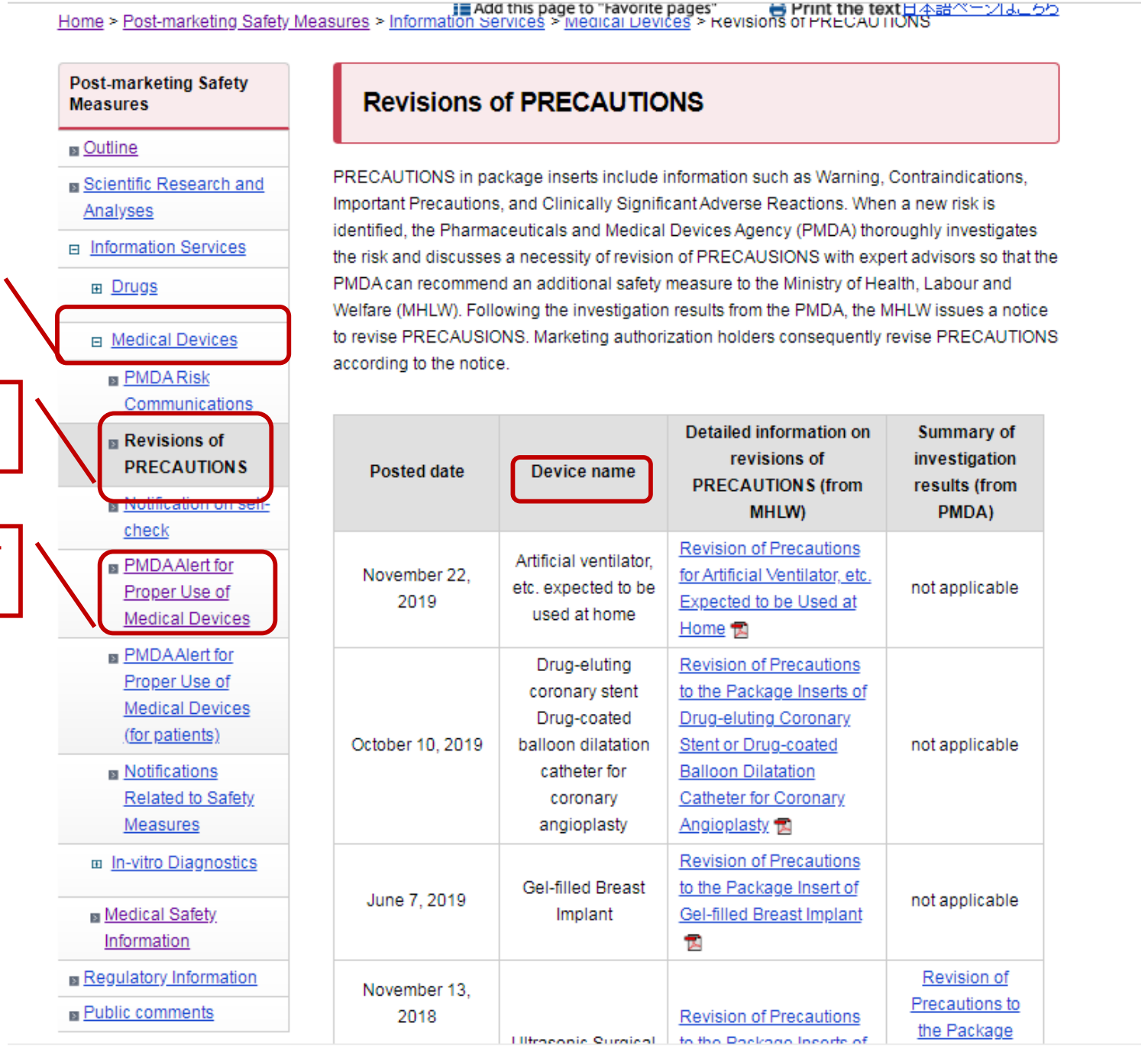
五、日本

- 网站：www.pmda.go.jp/english/safety/info-services/devices/0002.html

①：医疗器械

②：预防措施

③：警告信息



六、中国

- **警戒快讯网站**：http://www.cdr-adr.org.cn/ylqx_1/Medical_aqjs/Medical_aqjs_xxtb/
- 不良事件信息通报网址：http://www.cdr-adr.org.cn/ylqx_1/Medical_aqjs/Medical_aqjs_xxtb/

《医疗器械警戒快讯》数据库中所列不良事件主要收集的是美国FDA、英国MHRA、澳大利亚TGA以及加拿大Health Canada的警示或召回数据，并非境内上报数据；美国MAUDE数据库属于全数据库，只要按照FDA法规进行报告的MDR，都会录入该数据库；英国MHRA、加拿大Health Canada、澳大利亚TGA等关于医疗器械不良事件/召回/警戒信息的数据库会定时更新，可根据关键词进行进一步筛选，还可通过限制时间或限制关键词的位置等进行精确检索。

七、德国

- 网站：www.bfarm.de/SiteGlobals/Forms/Suche/EN/kundeninfo_Filtersuche_Formular_en.html?nn=4527724

advisory notice.

筛选报告日期

Ureteral Dilation Balloon C | all items | All dates | filter

1 search results

Date	Title
2019.01.16	**Urgent Field Safety Notice for Reverse Loaded Wire Guides by Cook Incorporated** Injections / Infusions / Transfusions / Dialysis - catheters

1

PDF 91KB

导出报告