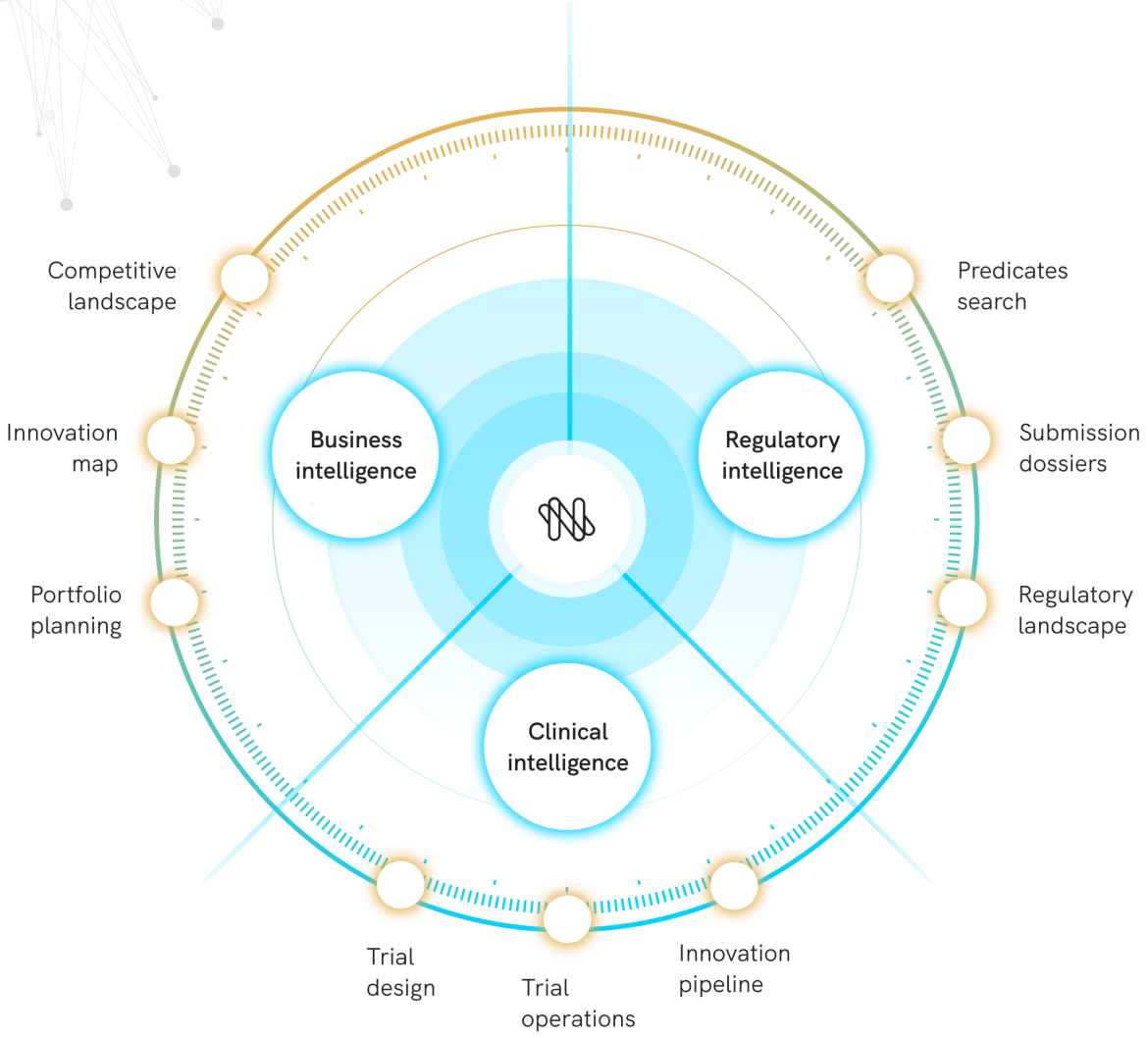
NyquistData

The leading intelligence platform for Medical Technology

855 El Camino Real Ste 13A - 286
Palo Alto, CA 94301
info@nyquistdata.com
https://www.nyquistdata.com
(833) 536-6888

About us

Nyquist Data's ready-to-use cloud-based AI solution provides data aggregation, workflow automation and predictive analytics to support strategic decision making in regulatory, R&D and commercialization for the life sciences industry.



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Our Product

Our platform provides industry-validated insights for business, clinical and regulatory intelligence on medical devices innovation approved by regulatory agencies across major markets and over 300,000 clinical trials conducted globally.

Geographic modules

- **US Module:** Over 60 years of historical data, 163,000+ devices and growing everyday. Search by indication and see the genealogy of various devices. All the data is connected from clinical trials to real-world evidence. From high-level overview to intricate details.
- **EU Module - Beta:** Over 47,000 devices from 1,250+ companies distributed in over 30 countries. Search by indication and browse devices by legislation and standards. New data is added everyday
- **Japan Module:** 110,000+ devices and close to 6,000 companies, with over 25 years of historical data. This is the only platform that provides original Japanese translated content. Navigate the Japanese records and reduce barriers to entry.
- **China Module:** 100,000+ devices and over 200,000 companies, with over 10 years of historical data. Enter a new market with an advantage – we are the only data provider of this information, which gives you access to first hand insights to a dynamic and exciting market.

Functional module

- **Clinical trial module:** Over 3 billion words from over 450,000 clinical trials. Our Clinical Trial Module provides data and analytics on trial design for all observational, surveillance and randomized clinical trials from over 200 countries.

- 3 Billion words analyzed from 450,000+ research studies in 200+ countries
- 285,000+ clinical investigators
- 1 million+ medical devices approved in major markets (US, EU, Japan and China)
- 61,000+ companies who have filed for device registrations
- 37,000+ approved manufacturing sites visualized on a global map
- 6.8 million+ adverse event reports
- 46,000+ medical device recall reports

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Our Solutions

We provide intelligent solutions for time-sensitive and hard-to-tackle business problems for the global MedTech community

Case example 1:

Finding the right predicate

- **Challenge:** Finding the right predicate is a key step in regulatory strategy. It requires a deep understanding of the features of the product and similar products that have previously been approved. A designation of “substantially equivalent” can often save months of time and money in a regulatory filing. Currently it is a cumbersome process that requires navigating different databases, being skillful in the search strategy and going through multiple iterations before landing on a short list of potential predicates

- **Solution:** NyquistData provides readily accessible data on all predicates of an approved device, with easy navigation to the predicate device profile and its associated predicates. This allows the researcher to quickly develop a map of potential predicates. This feature saves researchers from many hours of manual work collecting, verifying, and collating information on predicates from different databases.

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Case example 2:

Getting a short list of OEM manufacturers

- **Challenge:** Finding the right OEM for a component is often a challenge for medical device companies. The right OEM may be located in a different country, it may not be widely known, and there are various operational and strategic considerations before making any selection decisions. Innovation leads in medical technology companies often leverage industry contacts, Google searches, and personal networks to identify a list of potential leads. This process is time consuming and costly.

- **Solution:** Leveraging regulatory data previously hidden in volumes of filing documents, NyquistData connects approved manufacturers that are associated with any approved medical device. Using search strategies such as searching for similar devices, NyquistData provides a filtered list of potential OEM manufacturers. Visualization of the data on a global map allows users to quickly locate OEM manufacturers and gather data to assess other criteria for decision making.

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Customer testimonials

"I'm interested in improving our workflow and getting information that I need as quickly as possible. I'm impressed with the results generated from your product. When my team members tell me that they can find the information they need in 30 minutes instead of several hours, that saves us time and money."

Dan Schultz

PRINCIPAL, MEDICAL DEVICES & COMBINATION PRODUCTS, GREENLEAF HEALTH

"I use the NyquistData platform several times a week. I previously would search several different databases, use CTRL-F to find information, and verify again through Google. I could have easily missed something since it was harder to search using my previous methods. I feel that we get a more accurate result from this platform and I am more confident with the search results from NyquistData."

Sam Eakes

DIRECTOR, REGULATORY AFFAIRS, GREENLEAF HEALTH

"For my area of work in strategy development and innovation, we have a very limited set of database resources. Typically I have to do a lot of Google searches to find some information and spend significant time filtering the information to find useful insights. NyquistData really solved one of our urgent business problems by creating transparency and agility on some key information. I am so glad that I have the resources of NyquistData for my work."

Kelly Lu

PROGRAM DIRECTOR, CARDIAC RHYTHM MANAGEMENT, MEDTRONIC

"My work is unique in that I work with a team of engineers on projects at earlier stages of innovation. My role is to provide regulatory knowledge and input in the early planning phase. I use the NyquistData platform quite frequently and I find it to be a very user-friendly tool for potentially identifying novel pathways for the regulatory process. This tool has helped me save a tremendous amount of time and headache in my work."

Krystal Santiago

DIRECTOR RA/QA/CA, NXT BIOMEDICAL

We are trusted by the world's best companies

Medtronic · COOK MEDICAL · BD · Greenleaf Health · Johner Institut · ComeBack Mobility

NXT BIOMEDICAL · UCLA Biodesign Program · snapi · 3D PREDICT AI-DRIVEN ALIGNERS · 東京大学 THE UNIVERSITY OF TOKYO · 中国科学院 CHINESE ACADEMY OF SCIENCES

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Articles

The advantages of an AI/ML-enabled search engine for FDA records

The FDA released a list of cleared or approved artificial intelligence and machine learning-enabled devices in September, documenting much of the agency's work in the innovative area of AI/ML.

Extracting this information from the FDA's decades-old database is labor-intensive at best — and often impossible. Despite the time spent by the FDA to make this new list, a lack of even text-based searching capability makes the list itself cumbersome and time-consuming to review.

Wouldn't it be better if there was an AI resource that could quickly compile a list of FDA's AI/ML clearances and approvals, allowing searches in seconds rather than hours?

Like many databases, the FDA database uses text-matching to find relevant entries. The weakness of text-matching is that it doesn't match the search term as a whole. For example, if you search for "pain," all records containing "pain" will be reported — along with records containing "Spain" and "painting."

And text-matching often misses relevant results. When users search "pediatric," the FDA database won't search for other spellings such as "paediatric" or related terms such as "neonate," "newborn," "infant," "children" and so forth.

The strength of modern AI-powered searching algorithms is that they can understand the content and help users find what they are looking for. A JAMA paper published in July used a type of AI searching algorithm known as natural language processing (NLP) to identify an additional 23% of FDA database reports with patient deaths that were not classified as deaths using the text-match searching. Many of those misclassified reports never mentioned "death," but instead "patient expired" or "could not be resuscitated." This demonstrates the limitation of text-matching and why the medical device industry should switch to modern AI-powered methods, not just for database searching, but also to interrogate adverse event reporting, recalls, and application review details.

The authors used Nyquist Data's commercially available AI-powered searching engine to evaluate FDA's database with keywords "machine learning", "artificial intelligence", "deep learning" or "neural network." We only used the publicly available FDA database, which includes the summary files disclosed by the FDA. We quickly generated a list of 222 devices and compared it to the FDA's list, finding three key differences:

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1. Text-searching typically omits relevant citations.

NLP methods discovered more than 20 AI/ML devices that were not in the FDA's list but were approved earlier than June 2021. For example, the RapidScreen RS-2000 system approved in 2001 clearly stated it used an artificial neural network for classification, and the Pathwork Diagnostics Tissue Of Origin Test approved in 2008 also clearly stated it used a machine learning approach based on marker selection to build a predictive model.

2. A text-matching search will always be out-of-date compared to an AI-enabled search because of the speed of AI.

The latest device in FDA's list is the Precise Position from Philips, approved on June 17, 2021. According to our research, FDA approved at least 24 AI/ML devices after the list's cutoff date. FDA says it will periodically update the list, but an AI/ML enabled search engine using NLP algorithms can automatically update in milliseconds.

3. AI/ML search engines are more flexible, yet have clear search and exclusion criteria.

The FDA said it created its list "by searching FDA's publicly-facing information, as well as by reviewing information in the publicly available resources cited below and in other publicly available materials published by the specific manufacturers." How they searched the information and with which keywords is unclear.

Gili Pro BioSensor is on the list, but the publicly available Reclassification Order mentioned nothing about "machine learning" or "artificial intelligence," only that it uses an optical sensor system and software algorithms to obtain and analyze video signals and estimate vital signs.

The RX-1 Rhythm Express Remote Cardiac Monitoring System is also included but didn't explicitly say "machine learning" or "artificial intelligence." It did mention that an embedded algorithm processes the acquired ECG to detect arrhythmias, compress the ECG, and remove most in-band noise without distorting ECG morphology. There are at least 10 other ECG analysis devices included in FDA's list, but none explicitly mentioned "machine learning" or "artificial intelligence" in their public information. Assuming these examples belong on the list means the FDA may have employed personal knowledge of the devices in a time-consuming search, underscoring the deficiencies of text-matching searches.

> The strength of modern AI-powered searching algorithms is that they can understand the content and help users find what they are looking for

Filtering for further intelligence

Besides those differences between text-matching and AI algorithms, the AI results could be further interrogated to find interesting results. What if you wanted to know which AI/ML devices required a clinical trial for market clearance? The FDA's list requires that you individually call up each device, one by one, to review the content of the submission. Using Nyquist Data's commercially available AI search engine, the authors immediately developed a list of AI/ML devices and simultaneously filtered for descriptions of clinical trials.

Most AI/ML devices are radiological FDA clearances that did not require clinical trials to establish substantial equivalence to predicate devices. However, there are five AI/ML devices that submitted clinical trial data to support their claims of substantial equivalence or claims of safety and effectiveness: one in ophthalmology (K200667), one in microbiology (K142677) and three in radiology (P200003, DEN170073 and K183019). This information is critical to determining potential test criteria of innovations in the same fields. This additional searching takes milliseconds using a commercial AI search engine, but could take many hours using the FDA database search engine. In addition to the amount of work to use non-AI search algorithms, one cannot discount the loss of valuable information that is easily missed.

We are excited by the FDA's innovation, flexibility and intelligence demonstrated in approving/clearing medical devices associated with AI and ML. Their list improves regulatory intelligence for all.

Nonetheless, as regulatory professionals, we should be using AI/ML to unlock the FDA databases for improved regulatory intelligence. The higher quality regulatory intelligence that comes from the use of AI algorithms can result in better business practices in regulatory and clinical affairs, quality management, and business strategy development.

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