Smarte globale Zulassungsprozesse

Karim Djamshidi
Executive Director
Global Patient Health & Regulatory Compliance

OVERVIEW

1 Über uns

2 Beyond MDR

3 Beispiel und Impulse

4 Fragen und Diskussion

KARL STORZ — ENDOSKOPE

1

Über uns

STORZ
KARL STORZ — ENDOSKOPE

Facts and figures at a glance

Foundation

1945 in Tuttlingen (Germany)

Fields

Medical Technology

Business areas

Human & Veterinary Medicine

Production sites

Germany, USA, Estonia, Switzerland

8,300

Employees worldwide

1.97 billion

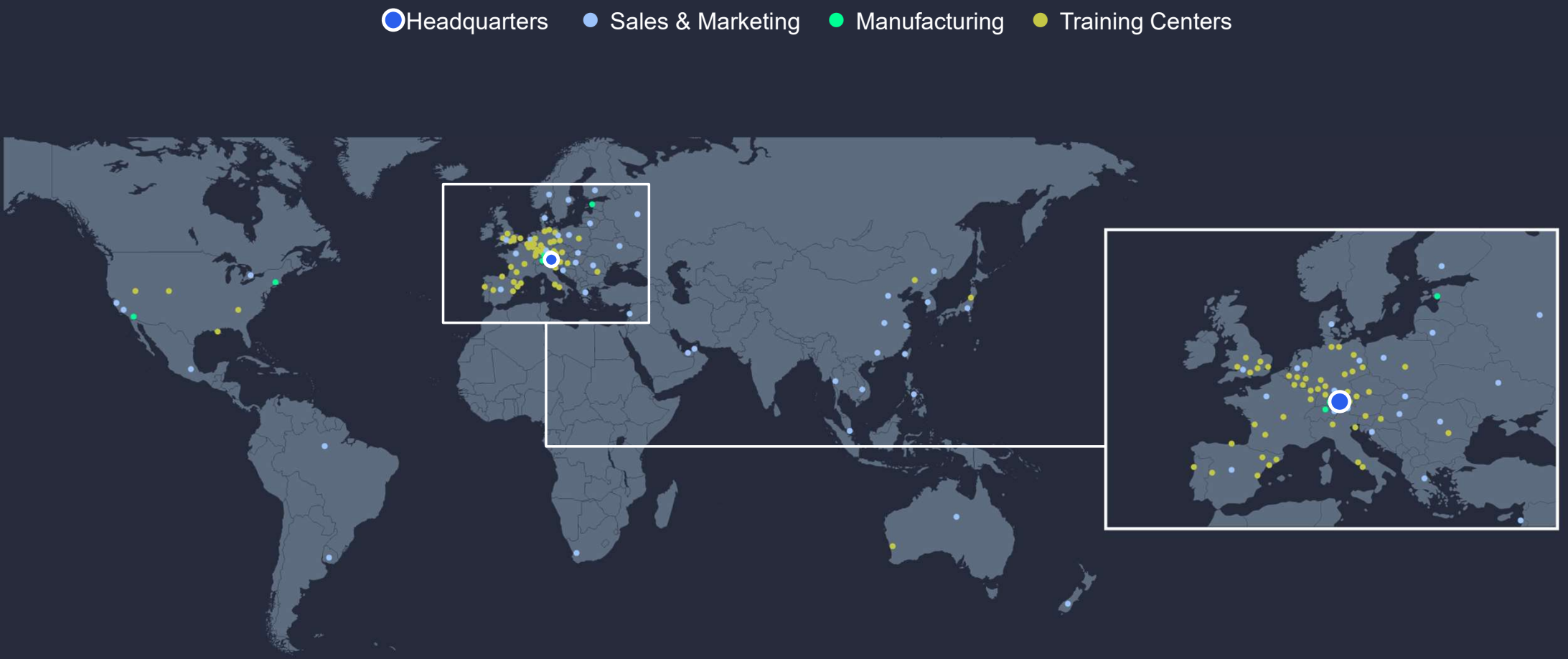
Euro turnover in 2021

70

subsidiaries in 40 countries

KARL STORZ—ENDOSKOPE

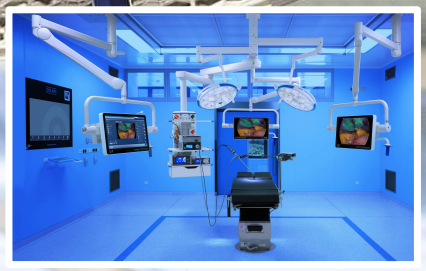
The world is our home

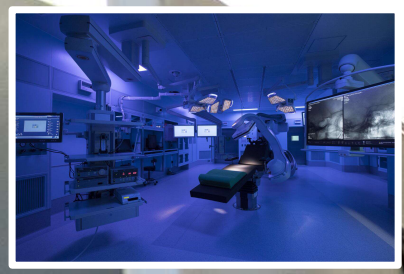


STORZ
KARL STORZ—ENDOSKOPE

Clinics worldwide value technologies from KARL STORZ

Leading clinics and healthcare partners worldwide rely on our innovations.





STORZ
KARL STORZ—ENDOSKOPE

Our company strategy

Our vision

We enable our healthcare partners to perform at their very best every day to improve patients' lives around the world. As an independent family-owned company, we continuously think in generations instead of quarters.

Our mission

We act as a solution-oriented and innovative partner in close collaboration with our customers. Through the experience and knowledge of our employees, we can expand into new markets, products and industries.

Overall strategic objective 2025+

We are a recognized leader in high-quality and innovative solutions that create unique value for our customers. Based on our success we sustainably increase revenues and profits.

STORZ
KARL STORZ — ENDOSKOPE

What we stand for: Our company values

Health & Safety
We put well-being and safety at the center of everything we do for patients, healthcare partners and our employees around the globe.

Integrity
We are trustful, compliant, committed and accountable.

Social responsibility
We care about our environment and give back to our communities.

Courage
We openly share our ideas and encourage strong and thoughtful decisions.

Self-reflection and continuous improvement
We act as a learning organization and embrace our failures to learn from them.

Respect
We treat everyone with respect and foster diversity.

STORZ
KARL STORZ — ENDOSKOPE

Pillars of endoscopy

Optics

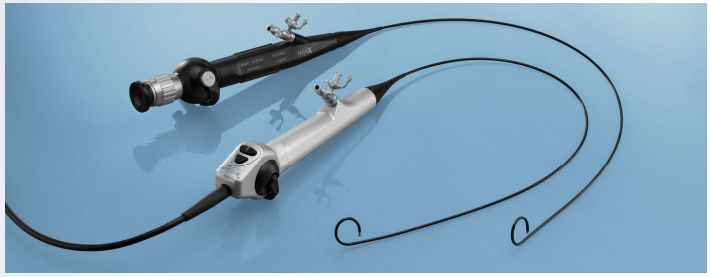
Mechanics

Electronics

Software

Complete solutions

STORZ
KARL STORZ — ENDOSKOPE



Over 75 years of expertise

- Rigid and flexible endoscopes, instruments and equipment
- Over 15,000 products
- Integrated system solutions such as OR1™ and OFFICE1
- 10,000 property rights

STORZ
KARL STORZ — ENDOSKOPE

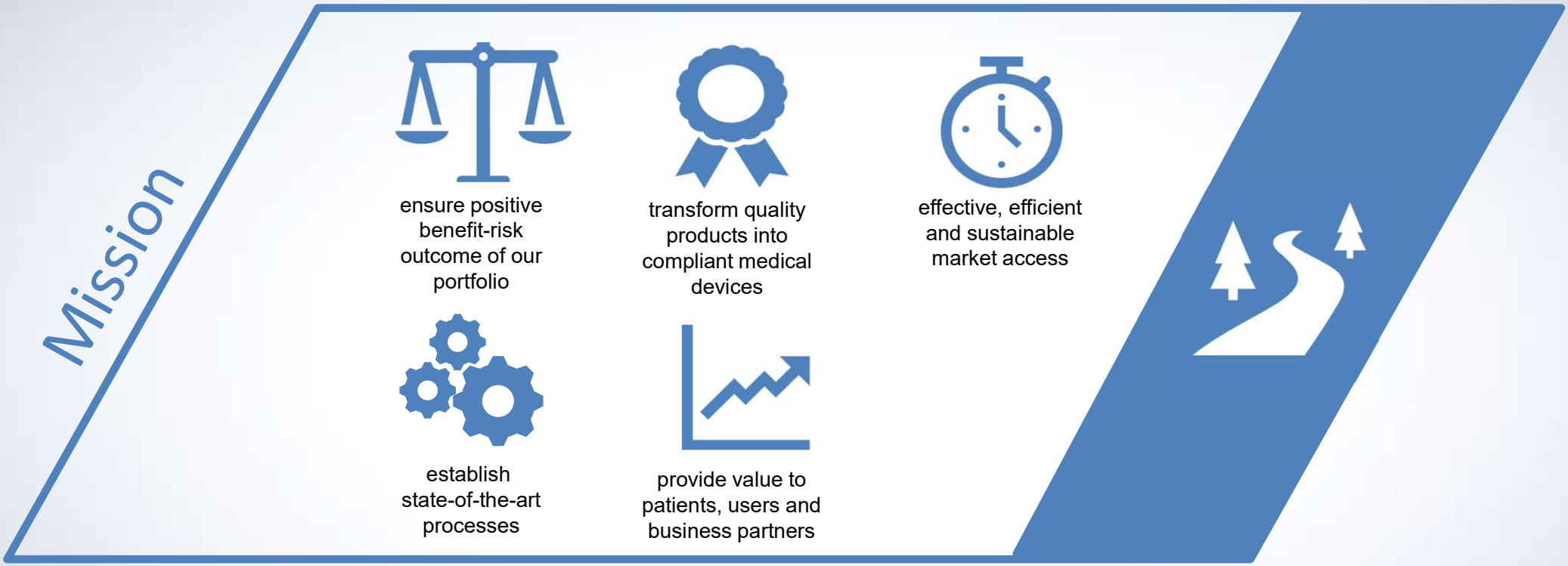
Human medicine: You are in good hands with us

Our specialties:

- Neurosurgery
- Oral and Maxillofacial Surgery
- Ear, Nose and Throat Medicine
- Plastic Surgery
- Anesthesiology and Emergency Medicine
- Cardiovascular Surgery
- Thoracic Surgery
- Laparoscopy
- Gynecology
- Urology
- Proctology
- Arthroscopy and Sports Medicine
- Spine Surgery
- Microscopy
- Pediatrics

STORZ
KARL STORZ — ENDOSKOPE

Global Patient Health & Regulatory Compliance



We enable KARL STORZ worldwide
to achieve all goals and reduce all patient, user and regulatory risks by establishing sustainable processes and structures.

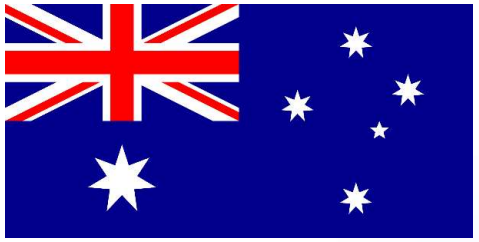
STORZ
KARL STORZ — ENDOSKOPE

2

Beyond MDR

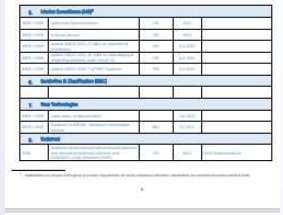
STORZ
KARL STORZ—ENDOSKOPE

Upcoming Changes



STORZ
KARL STORZ—ENDOSKOPE

Regulatory VUCA World



RSS

August 22, 2022 UPDATED PMDA-ATC Seminar schedule has been updated

August 22, 2022 NEW The 5th Subcommittee on Therapeutic Products Based on Extracellular Vesicles (EVs) Including Exosomes

August 19, 2022 NEW List of Approved Products: FY2021 (April 2021 - March 2022)

August 19, 2022 NEW English Translation of Review Report: Jyseleca

August 8, 2022 PMDA-ATC Medical Devices Webinar 2022 - Explanation of/Insight into IMDRF documents

NMPA Announcement on Two Guidelines for Registration Review of Drug-Device Combination Products with Device Taking Primary Mode of Action

2022-01-17

National Medical Products Administration has set the technical evaluation of drug-device combination products as a research project in regulatory science, and organized to formulate the Guideline for Registration Review Drug-Device Combination Products with Device Taking Primary Mode of Action and the Guideline for Registration Review of Qualitative, Quantitative and In Vitro Release Studies of Drugs in Drug-Device Combination Products with Device Taking Primary Mode of Action.

NMPA Announcement on the Emergency Approval Procedure for Medical Devices

2021-12-29

National Medical Products Administration organized to revise the Emergency Approval Procedure for Medical Devices, which is issued and take effect as of December 29, 2021.

NMPA Notice on Matters Concerning the Registration of Drug-device Combination Products

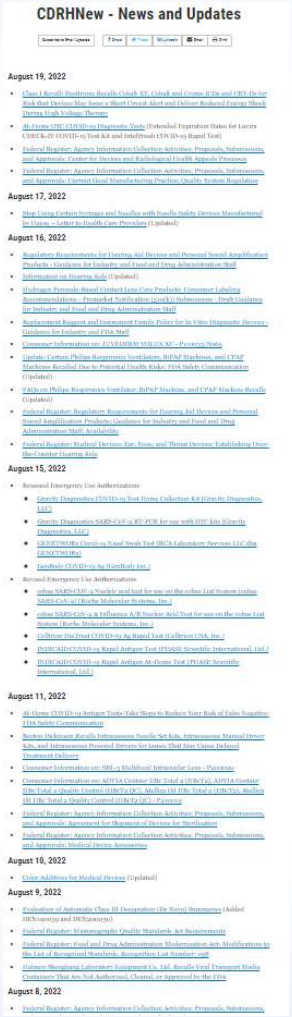
2021-07-27

ation management of drugs and medical devices,
e combination products are hereby announced on July

6 Guidance including the Guidance
Names of Medical Rehabilitation

lance including the Guidance for Nomenclature of the
s, which are issued on July 12.

S.no	Title	Release Date	Download Pdf	Pdf Size
1	List of the Certified Medical Device Testing Laboratory under MDR, 2017	2022-Aug-17		5938 KB
2	Classification of Medical Device Pertaining to Rehabilitation under the Provisions of Medical Devcies Rules 2017	2022-Aug-04		852 KB
3	Notice dated July 11 2022	2022-Jul-11		370 KB
4	Classification of Medical Device Pertaining to Dental Under the provision of Medical Devices Rules 2017	2022-Jun-03		898 KB
5	Classification of Medical Device Pertaining to Obstetrical and Gynecological Under the provision of Medical Devices Rules 2017	2022-Jun-03		529 KB
6	Classification of Medical Device pertaining to General Hospital under the provisions of Medical Devices Rules 2017	2022-Mar-16		813 KB
7	List of Notified Bodies registered with CDSCO under MDR, 2017	2022-Mar-11		738 KB
8	Regulation of CT scan equipment_All Implantable Devices_MRI equipment etc. as Drugs with effect from April 1st 2021	2021-Nov-03		246 KB
9	Registration and Labelling requirements of Medical Devices	2021-Sep-28		366 KB
10	Classification of Medical Device pertaining to Neurological under the provisions of Medical Devices Rules, 2017	2021-Sep-28		367 KB



- MDR ist eine Chance und eines von vielen Beispielen
- Alltäglichen Regulatorischen Herausforderungen sind nun vor der Haustür
- Die CE Konformität berechtigt lediglich zum in Verkehr bringen in der EU
- Andere Märkte andere Gesetze

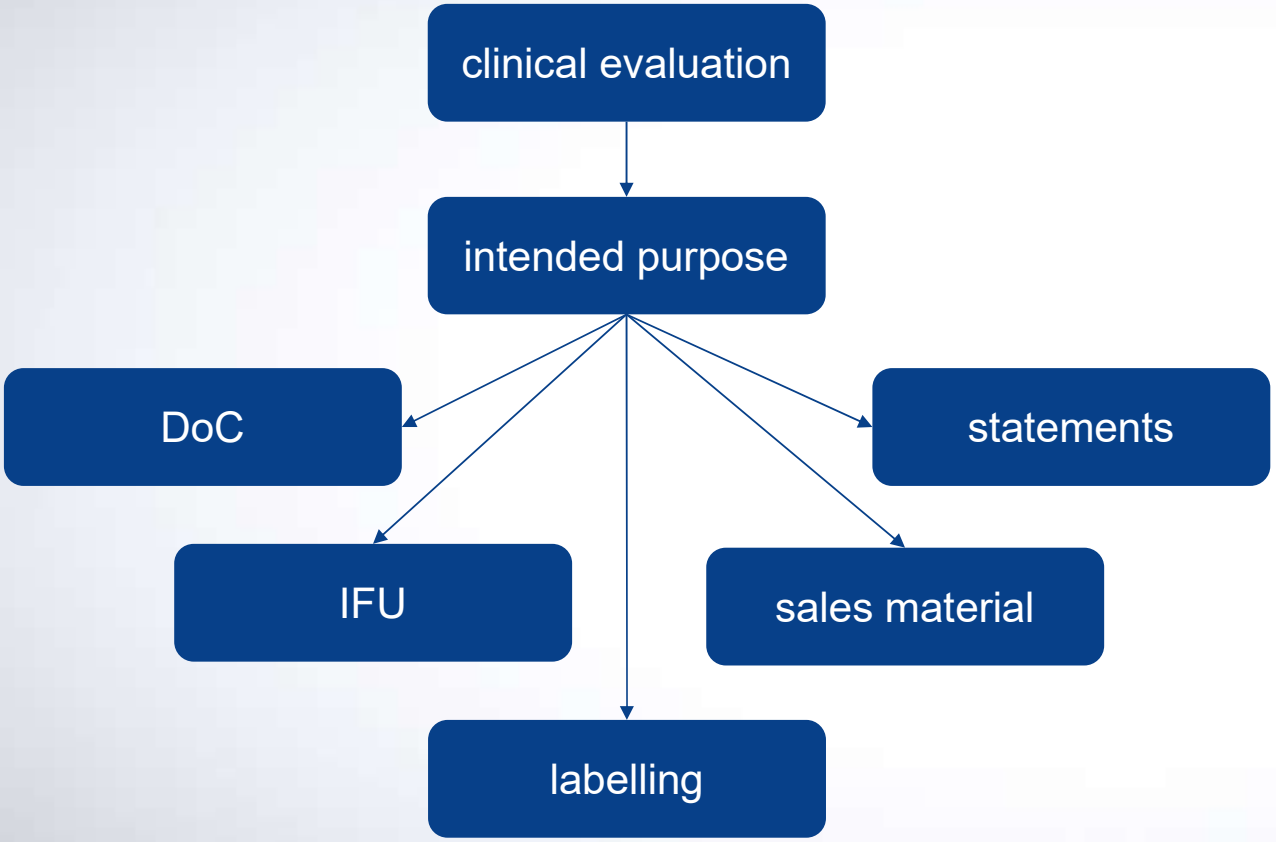
STORZ
KARL STORZ—ENDOSKOPE

3

Beispiele und Impulse

STORZ
KARL STORZ—ENDOSKOPE

EU MDR Zweckbestimmung



‘**intended purpose**’ means the **use** for which a device is **intended** according to the data supplied by the manufacturer on the label, in the instructions for use or in promotional or sales materials or statements and as specified by the manufacturer in the **clinical evaluation**;

(MPVO 2017/745 Arikel 2 (12)

KARL STORZ—ENDOSKOPE

Zweckbestimmung: Clinical vs. Regulatory

Was soll diagnostiziert, therapiert, überwacht, gelindert oder vorhergesagt werden?
Welche Indikation müssen vorliegen bzw. wann ist das Produkt kontraindiziert?
Welche Patientenpopulation darf an welchem Körperteil durch wen behandelt werden?
Wie muss Gebrauchsumgebung bzw. Nutzungsumgebung aussehen?
Wie funktioniert das Produkt?
Welchen Nutzen und Risiken gibt es?

Welche Regularien gelten?
Handelt es sich um ein Medizinprodukt?
Wie ist die Risikoklasse des Medizinprodukts?
Welches Zulassungs- oder Konformitätsbewertungsverfahren wähle ich?
Welche Grundlegenden Sicherheits- und Leistungsanforderungen gibt es?
Wie ähnlich ist ein Produkt zum „predicate device“ für die „substantial equivalance“?
Wie gruppiere ich das Produkt?

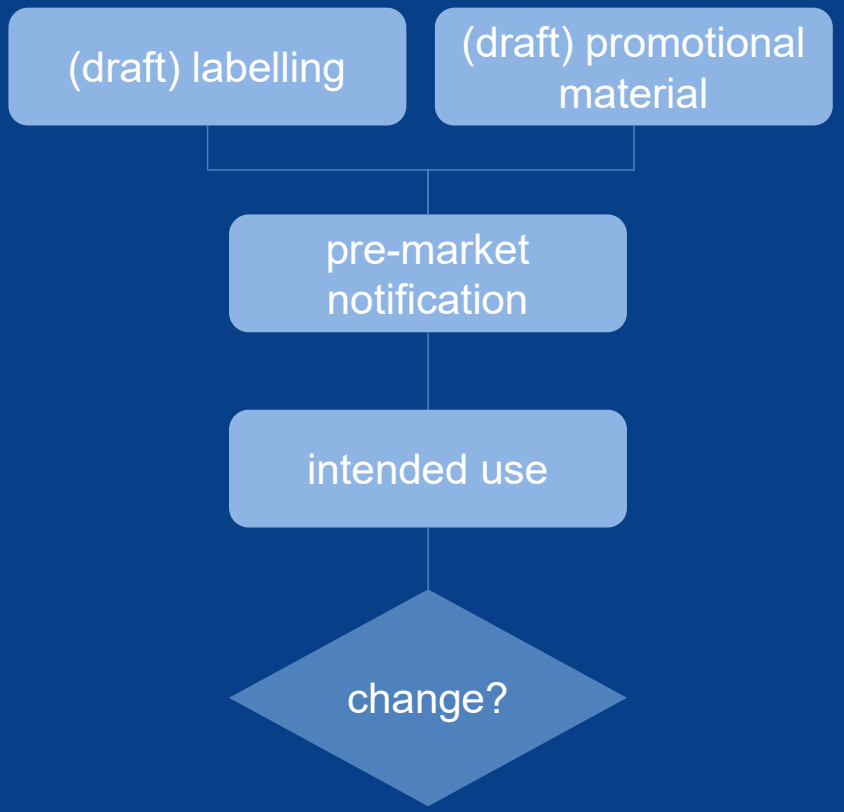
wissenschaftlich detaillierte Ansatz

vordefinierter genereller Ansatz

STORZ
KARL STORZ — ENDOSKOPE

510(k) Summary

(4) A description of the device that is the subject of the premarket notification submission, such as might be found in the **labeling** or **promotional material** for the device, including an explanation of how the **device functions**, the **scientific concepts** that form the basis for the device, and the significant **physical** and **performance characteristics** of the device, such as device design, material used, and physical properties;
(5) A statement of the intended use of the device that is the subject of the premarket notification submission, including a general description of the **diseases or conditions** that the device will **diagnose**, **treat**, **prevent**, **cure**, or **mitigate**, including a description, where appropriate, of the **patient population** for which the device is intended. If the **indication statements** are different from those of the legally marketed device identified in paragraph (a)(3) of this section, the 510(k) summary shall contain an explanation as to why the differences are not critical to the intended therapeutic, diagnostic, prosthetic, or surgical use of the device, and why the differences do not affect the safety and effectiveness of the device when used as labeled; and
(6) If the device has the same **technological characteristics** (i.e., design, material, chemical composition, energy source) as the predicate device identified in paragraph (a)(3) of this section, a summary of the technological characteristics of the new device in comparison to those of the predicate device. If the device has different technological characteristics from the predicate device, a summary of how the technological characteristics of the device compare to a legally marketed device identified in paragraph (a)(3) of this section.
(CFR21 Sec. 807.92)



STORZ
KARL STORZ—ENDOSKOPE

Länderspezifische Zweckbestimmung

Suction/irrigation pumps and their accessories are used for the introduction of irrigation fluids into organs, joints and operating fields as well as the suctioning off of irrigation fluids and bodily fluids, secretions, tissue and gas during diagnostic or therapeutic interventions.

The product is intended to:

- provide the infusion of the sterile irrigant solutions into the ureter and upper urinary tract, as well as to suction off the irrigation fluids, bodily fluids, secretions, tissue and gas during diagnostic and operative endoscopic urological procedures
- provide the infusion of the sterile irrigant solutions into the uterus, as well as to suction off the irrigation fluids, bodily fluids, secretions, tissue and gas during diagnostic and operative endoscopic hysteroscopic procedures
- provide the infusion of the sterile irrigant solutions into organs and operating fields during diagnostic and operative procedures in laparoscopic and open general surgery
- provide sustained liquid irrigation and distention of joint or intra-articular spaces during all phases of arthroscopic surgery
- provide the infusion of the sterile irrigant solutions in order to enable the Lens Cleaning during endoscopically assisted Functional Endoscopic Sinus Surgery and endoscopically assisted transnasal pituitary gland surgery

…

Saug-/Spülpumpen dienen zum Einbringen von Spülflüssigkeiten in Organe, Gelenke und auf Operationsfelder sowie zum Absaugen von Spül-, und Körperflüssigkeiten, Sekreten, Gewebe und Gasen. Saug-/Spülpumpen haben keinen Körperkontakt.

Das Produkt stellt Spül- oder Saugfunktionen für folgende Fachgebiete bereit:

– Urologie
– Gynäkologie
– Chirurgie (Thorakoskopie, Laparoskopie und Proktologie)
– Arthroskopie
– Wirbelsäulenchirurgie

Darüber hinaus kann die Pumpe mit Saug und Spülfunktion zur Linsenreinigung von Endoskopen genutzt werden.

Zu den Spezifikationen des Produkts, siehe Kapitel Technische Daten.

STORZ
KARL STORZ — ENDOSKOPE

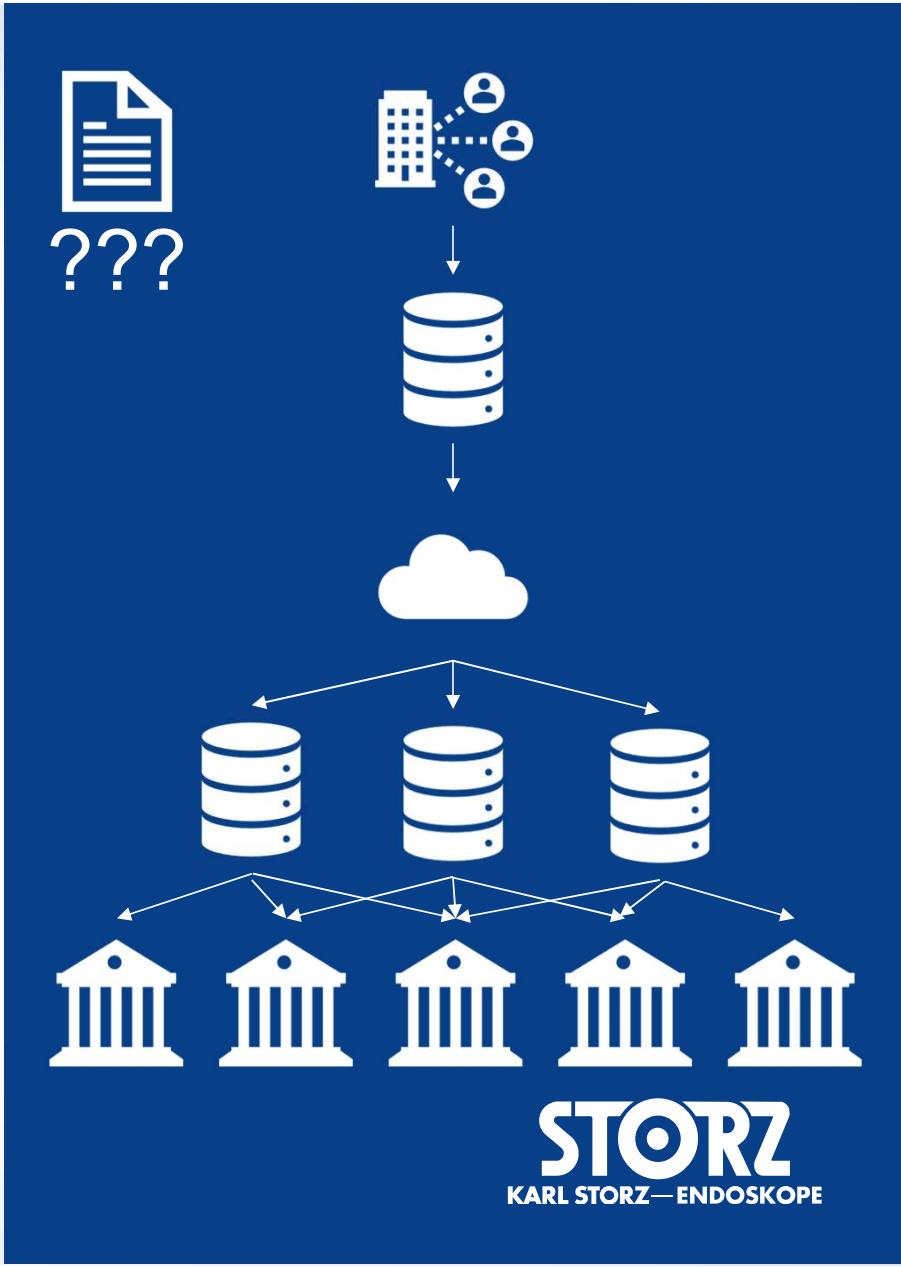
Zweckbestimmung als Datenmodell

STORZ
KARL STORZ — ENDOSKOPE

Wenn die Zweckbestimmung aus Daten bestünde…

… könnten sich Zulassungen leicht ableiten
… würden Länderinformationen konsistent gehalten
… könnten (UDI) Datenbanken leicht befüllt werden
… wären Produkte leicht zu codieren und gruppieren
… wäre sie überall in der technischen Dokumentation gleich
… könnten Änderungen leicht bewertet werden
… wäre die Spezifikationen leichter rückverfolgbar
… ließen sich Listen von Behörden leicht befüllen
…

Warum nicht?



Change Management DIN A4

Past Present Future

Beispiel Softwarechange „Neuer Urologie Modus“

Beispiel Sterilisiererwechsel Schlauchset

STORZ
KARL STORZ — ENDOSKOPE

4

Q&A

STORZ
KARL STORZ—ENDOSKOPE

Thank you for your attention!

KARL STORZ — ENDOSKOPE