## Case Study:

# Registration of a Software as medical device in China, Columbia and South Korea for European AI based Company

**Client**
A global company developing Artificial Intelligence based Software for Medical Application for Dental, Orthopedic and Surgical applications.

**Products**

- An AI based software used for DXA analysis and clinical examination.
- Used in combination with bone densitometer for potential fracture risk analysis
- Used for monitoring effect of treatment over a period

**Product Categories**
Class IIa Medical Devices (Software)

**Countries of Interest**
Columbia, China and South Korea

**Services Provided**

- Preparation and Submission of Dossier
- Local Representation
- Assisting with Local Testing
- Regulatory Intelligence

**Client Situation**

The Client is a US based medical device company that developed a suite of innovative AI based software for multiple applications. The client has registered the software as medical devices in EU, USA, Canada, Australia, Brazil, Japan, Thailand and had planned to register in 10+ other global markets. With limited global presence and regional regulatory expertise, Client wanted a global partner to ensure their product approval in markets of interest.

**GRP Solution**

GRP with its extensive global experience with Artificial Intelligence based software as devices and regional presence across Americas, Asia-Pacific, Europe was preferred by client as one-stop-shop for all their regulatory and clinical needs. GRP was able to provide a harmonized global strategy for device registration in priority markets based on country specific timelines and documentation / testing requirements. GRP obtained licenses successfully in those markets and continues to be a partner to help Client expand in global markets. GRP services included the following:

| Regulatory Strategy | Dossier Preparation and Submission | Approval and Maintenance |
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| Assess Client's product dossier, regulatory assessment and develop harmonized strategy for Columbia, China and South Korea<br><br>Local Representation in China, South Korea<br><br>Prepare local testing plan in China | • Preparation of dossier using Free Sale Certificate, FDA's CFG, IFU, EU Declaration of Conformity, V&V Test Reports as per IEC 62304, Risk Management Summaries per ISO 14971, FMEA Matrix, KGMP/ GMP Audit Certificate ISO 13485 Certificate and as per CFDA, STED and other guidelines<br>• Assist with local product testing in China<br>• Submission of registration dossier and applications | • Obtain approval in countries as per timelines<br>• Manage lifecycle of products with CFDA, MFDS<br>• Manage complaints and recall related activities<br>• Report adverse events in countries<br>• Manage HA queries<br>• Regulatory Intelligence for proactive advice of changes |

**Key Highlights**

- Client could implement a detailed global strategy for software as device registration using GRP's plan and global presence
- Client could obtain timely registration in markets of interest
- GRP continues to work as Client's partner in managing licenses for end to end post approval requirements

- GRP's experience with Client's software enabled it to take ownership of additional global markets increasing client's revenue while ensuring global compliance

*Keywords: Artificial Intelligence, Software as Device, Columbia, China, South Korea, Registration, Local Representation, MFDS, CFDA, STED, Class II*