“Regulatory Status of Premarket Submission and Approval Requirements in Mexico”.
Topics:

1. Strategies taken by the Mexican government to streamline the process and reduce the regulatory burden.
2. Approval Requirements for the Ordinary Lane and Authorized Third Parties
3. Approval Requirements for the Equivalence Agreement FDA/HC
4. Approval Requirements for the Equivalence Agreement Japan
5. Agreement for Low Risk Medical Devices
LEGAL FRAMEWORK

Constitution of the Mexican United States
General Health Law (LGS)
Regulation of Health Products (RIS)
Pharmacopoeia of the Mexican United States (FEUM)
Official Mexican Norms
Agreements
Guidelines
STRATEGIES TAKEN BY THE MEXICAN GOVERNMENT TO STREAMLINE THE PROCESS AND REDUCE THE REGULATORY BURDEN ON THE APPROVAL OF MEDICAL DEVICES IN MEXICO
Mexico has a Traditional Line to submit a medical devices dossier with the necessary information to comply with the Mexican Law, however, in the last 4 years strategies were designed to streamline the process and reduce the regulatory burden on the approval of medical devices:

- Equivalence Agreement FDA/HC (30 business days to obtain a Response)
- Equivalence Agreement with Japan (30 business days to obtain a Response)
- Agreement for Low Risk Medical Devices (reduce the regulatory burden for medical devices consider in Mexico to have Low Risk)
- Authorized Third Party (15 business days to obtain a Response, Pre-review)
REQUIREMENTS FOR THE APPROVAL OF MEDICAL DEVICES BY THE TRADITIONAL LINE AND AUTHORIZED THIRD PARTIES
ADMINISTRATIVE REQUIREMENTS:

1. Registration Application Form.

2. Proof of Payment of fees (Class I, II or III, as appropriate)

3. Copy of Notice of Retail Operation in Mexico and Copy of Notice of Health Responsible.
GENERAL REQUIREMENTS:

• Brand Name
• Generic Name
• Intended of Use.
• Description of the Medical Device.
• Category (art. 262 L.G.S.)
• Class I, II or III (Art. 83 RIS)
• Presentations (including codes and description)
• Project Tag according to the established in the NOM-137-SSA1-2008, “Labeling Medical Devices”
SCIENTIFIC AND TECHNICAL INFORMATION

- Insert of Use:
  - Description, intended of use, components, storage, warnings, contraindications, adverse events, etc.

- Operational Manual
  - Description, intended of use, components, operation, calibration, warnings, etc.

*When all fails, read the insert of use*
SCIENTIFIC AND TECHNICAL INFORMATION:

• Technical Drawings or diagram of functional parts
  ▪ The drawing need to contain the material specifications and indicate the parts that come into contact with the patient

• Medical Devices with a Formula:
  Quali-quantitative Formula

• Raw Material:
  Information of the Active Ingredient that includes the chemical name, generic, physical and chemical structure, specifications, certificate of Analysis for the Raw Materials to demonstrate that ensures the safety of the product.
SCIENTIFIC AND TECHNICAL INFORMATION:

• Manufacturing Flow Chart

• Certificate of Analysis of the product: It's the report with results for a specific batch number (serial number) of the product, this document has to correlate with the Final release specifications and prove the safety and efficacy of the product, the CoA needs to be submitted on letterhead, signed by the person responsible of the quality (in the manufacturing site) and with translation to Spanish.
SCIENTIFIC AND TECHNICAL INFORMATION:

- Description of the sterility process
  - Complete Sterilization Process Protocol
  - Certificate of Sterilization

- Stability
  - Complete Stability Studies in real time and accelerated, Issued by the manufacturer with which endorses expiration date.

- Complete reports of biocompatibility studies conducted to the product or raw materials of the product, if applicable.
SCIENTIFIC AND TECHNICAL INFORMATION:

- Packaging information: Technical information regarding the packaging material (Primary and Secondary)
  - Must present the hermeticity test for sterile Medical devices in contact with the patient
- Report of Technolvigilance: information on adverse events that have been introduced during marketing or use, issued by the manufacturer on letterhead, signed by the person responsible of product quality (Manufacturing Site) with a simple Spanish translation.
- Complete clinical studies and a copy of the publication.
• Original or certified copy of the Free Sale Certificate issued by the health authority of the country of origin, which guarantees the product to be registered (and their codes), legalized (Apostille / consularized) and translated into Spanish (Legal translation).
FREE SALES CERTIFICATE

1. Authenticated (Apostille/Consularized).
2. Legal translation
3. Original or Certified Copy
LEGAL DOCUMENTS

• Original or certified copy in original Certificate of Good Manufacturing Practices (ISO 13485, CE Mark) that endorses the actual manufacturing sites, duly legalized (Apostille / consularized) and translated into Spanish (Legal translation).
CERTIFICATE OF GOOD MANUFACTURING PRACTICES

1. Authenticated (Apostille/Consularized).
2. Legal translation
3. Original or Certified Copy
• Original or certified copy of the **Letter of Representation** issued by the manufacturer's letterhead and signed sheet. It is very important that this letter specify that the Distributor in Mexico will market, distribute, import, and make the necessary arrangements with COFPRIS, and if necessary to be authorized renaming him or the products, properly legalized (Apostille / Consularization) and translated into Spanish (Legal translation)
LETTER OF REPRESENTATION

1. Authenticated (Apostille/Consularized).

2. Legal translation

3. Original or Certified Copy
EQUIVALENCE AGREEMENT FDA/ HEALTH CANADA
CLASSIFICATION IN ACCORDANCE TO THE COUNTRY OF ORIGIN OF THE APPROVAL

FDA
- Class 1
- Class 2
- Class 3

Health Canada
- Class 1
- Class 2
- Class 3
- Class 4

Important: Class 1 of Health Canada is Not included in this Agreement
GENERAL REQUIREMENTS

1. Registration Application Form.
2. Proof of Payment of fees (Class I, II or III, as appropriate)
3. Copy of Notice of Retail Operation in Mexico and Copy of Notice of Health Responsible.
4. Project Tag according to the established in the NOM-137-SSA1-2008, “Labeling Medical Devices”
5. Insert of Use / Operational Manual
6. Certificado de Análisis
7. Letter of Representation
8. Monography (Technical and Scientific Information)
The intended of use and the Description of the Device must correspond to those authorized by FDA/HC.
Que incluya:

1. Protocol
2. Methodology
3. Results
4. Conclusions
5. Report Number and Date
6. Especific if the studie was made for the final product or for each raw material.
9. Sterilization Method:

- Summary of the Sterilization Method.
- Summary of the Sterility Validation Process
- Conclusions.

10. Packaging information: Technical information regarding the packaging material (Primary and Secondary)
11. Stability Studies (Shelf Life):

- Summary with Results of the studies made in real time and/or accelerated that demonstrate the shelf life proposed by the manufacturer

- Methodology
- Results
- Conclusions
12. Clinical Studies. (Current)

- Studies of Security and Efficacy:
  - Summary and conclusions of the published clinical studies.

13. Bibliography
• Certificate to Foreign Goverment - CFG

Including ALL the devices to register
• Codes
• Description

Establishment name and Address of place of manufacture

= Project Tag (Label)

= Inspection Report (EIR)
• Certificate to Foreign Government - CFG

1. Authenticated (Apostille).

2. Legal translation

3. Original or Certified Copy
## Establishment Inspection Report - EIR

<table>
<thead>
<tr>
<th>Establishment name and Address of place of manufacture</th>
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</thead>
<tbody>
<tr>
<td>FEI: XXXXXXXX El Start: XX/XX/XXXX El End: XX/XX/XXXX</td>
</tr>
</tbody>
</table>

### TABLE OF CONTENTS

- SUMMARY
- ADMINISTRATIVE DATA
- HISTORY
- INTERSTATE COMMERCE
- JURISDICTION
- RESPONSIBILITY
- MANUFACTURING / DESIGN OPERATIONS
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- REFUSALS
- GENERAL DISCUSSION WITH MANAGEMENT
- INSPECTIONAL GUIDANCE
- VOLUNTARY CORRECTIONS
- EXHIBITS AND SAMPLES COLLECTED
- ATTACHMENTS

### SUMMARY

- Written by
- Date

### Observations and corrective actions

- Tag
- CFG

### Inspection number (FEI)

- Most recent inspection date
• Establishment Inspection Report - *EIR*

1. Authenticated (Apostille).

2. Legal Translation.

3. Simple Copy
• FDA approval
  a) Exempt to special controls
  b) 510(k)
  c) PMA
• FDA Approval - EXEMPTS

Annual establishment registration with FDA and Device Listing.
• FDA Approval - EXEMPTS

Device information, classification y exempt status.

( Establishment Registration & Device Listing)
### FDA Approval—Notification 510(k)

<table>
<thead>
<tr>
<th>Establishment Name</th>
<th>Classification</th>
<th>Medical Device Name</th>
<th>Approval (Substantially Equivalent)</th>
<th>Intended use of the device</th>
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</thead>
<tbody>
<tr>
<td>XXXXXXXX xxx x xxx</td>
<td>XXXXXXXXXXXxxxx</td>
<td>XXXXXXXXX</td>
<td>No. 510(K)</td>
<td>Re: KXXXXXX</td>
</tr>
<tr>
<td>XXXXXXXXXXX xx xxx</td>
<td>xxx XXXX xxx xxx</td>
<td>xxx</td>
<td>XX</td>
<td>Trade/Device Name: XXXXXXXXXXX xx xxx</td>
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<tr>
<td>XXXXXXXXXXXX XX xxx</td>
<td>Regulation Number: XXXX XXXX XX</td>
<td>Regulation Name: XXXX XX xxx</td>
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<td>XXXXXXXXX</td>
<td>Date: XX XXXX</td>
<td></td>
<td></td>
<td>Product Code: XXX</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Received: XXXXXXXXX xx XXXX</td>
</tr>
</tbody>
</table>

**From:**

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the application to legally marketed predicate devices marketed to U.S. commerce prior to May 28, 1976, the enactment date of the Federal Food, Drug, and Cosmetic Act (Act)) that does not require approval of a premarket approval application (PMA).

You may market the device, subject to the general controls provisions of the Act. This general control provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibition against adulteration and misbranding.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish Federal announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantially equivalent determination does not mean that FDA has made a determination that your device complies with all the requirements of the Act or any Federal statute and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 U.S.C. Part 807); labeling (21 CFR Part 820); good manufacturing practice requirements set forth in the quality systems (QS) regulations (21 CFR Part 820); and, if applicable, the electronic product radiation control provisions (sections 531-542 of the Act, 21 CFR 1000-1005).
FDA Approval — Premarket Approval PMA

Establishment Name
PMA Number
Classification
Approval

Name of Medical Device
Intended use of the device
• FDA Approval

1. Authenticated (Apostille).

2. Legal translation

3. Simple Copy
• **Technovigilance** (Only FDA class II and III)

  – Adverse Incidents.
  – Recalls
  – Corrective Actions and Conclusions
  – Declaration if not existent
  – Signed by Manufacturer.

  – “Postmarket Surveillance”

Technovigilance Report
• Technovigilance (Only FDA class II and III)

1. Issued by the manufacturer in letterhead and signed by responsible the quality of the product

2. Original or Certified Copy
FDA Requirements for CLASS 1 DEVICES

CFG

Establishment Inspection Report

FDA Approval: ER&L, 510(k), PMA
FDA Requirements for CLASS 2 and 3 DEVICES

- CFG
- Establishment Inspection Report
- FDA Approval: ER&L, 510(k), PMA
- Technovigilance Report
SPECIFY REQUIREMENTS FOR MEDICAL DEVICES

HEALTH CANADA
• Medical Device License

License number

Issuing Date

Establishment name and Address of place of manufacture

= Project Tag (Label)

Classification

Name of Medical Device

Including ALL devices to register

• Codes
• Description
• Medical Device License

1. Authenticated (consularized).

2. Legal Translation

3. Original or Certified Copy
• Certificate CAN/CSA ISO13485:03
• Certificate CAN/CSA ISO13485:03

- Certificate number
- Establishment name and Address of place of manufacture
  = Project Tag (Label)
- Issuing Date
- Expiration Date
- Certification Standard (13485)
- Standards Council of Canada Seal

• Issued by Authorized Third (“Registrar”)
• Certificate CAN/CSA ISO13485:03

1. Authenticated (Apostille / consularized).

2. Legal Translation

3. Simple Copy
• ISO 17021 (Authorized Third)

Accreditation Program
Management Systems

• Issued by the Standards Council of Canada (SCC)

• Legal Name of Authorized Third
  = Certificate ISO13485

• Authorized Third Address

• Other Addresses

• Accredited under ISO 17021 to issue certificates
  ISO 13485 (CMDCAS)
• Current Authorization (Authorized Third)

- Certificate of Accreditation
- Issued by the Standards Council of Canada (SCC)
- Legal Name of Authorized Third

= Certificate ISO13485

- Authorized Third Address
- Certificate Number
- Issuing Date
- Expiration Date
Current Authorization (Authorized Third)

1. Authenticated (consularized).

2. Legal Translation

3. Original or Certified Copy
Health Canada Requirements for CLASS 2, 3 and 4 DEVICES

- Medical Device License
- ISO 13485:2003 Certificate
- ISO 17021
- Authorization Authorized Third
EQUIVALENCE AGREEMENT JAPAN
### MEDICAL DEVICES APLICABLES AL ACUERDO DE EQUIVALENCIAS CON JAPÓN
#### CLASIFICACIÓN JAPONESA

<table>
<thead>
<tr>
<th>Clase</th>
<th>Categoría</th>
<th>Aprobación o Certificación</th>
</tr>
</thead>
<tbody>
<tr>
<td>II</td>
<td>Designated Controlled Medical Device</td>
<td>Certification Request to a Registered Certification Entity</td>
</tr>
<tr>
<td>II</td>
<td>Controlled Medical Device</td>
<td>Approval Request to PMDA/MHLW</td>
</tr>
<tr>
<td>III</td>
<td>Highly Controlled Medical Device</td>
<td>Approval Request to PMDA/MHLW</td>
</tr>
<tr>
<td>IV</td>
<td>Highly Controlled Medical Device</td>
<td>Approval Request to PMDA/MHLW</td>
</tr>
</tbody>
</table>
GENERAL REQUIREMENTS

1. Registration Application Form.
2. Proof of Payment of fees (Class I, II or III, as appropriate)
3. Copy of Notice of Retail Operation in Mexico and Copy of Notice of Health Responsible.
4. Project Tag according to the established in the NOM-137-SSA1-2008, “Labeling Medical Devices”
5. Insert of Use / Operational Manual
6. Letter of Representation
• **Certification** issued by the Registered Certification Entity, including the sheets where the following topics are specified:

  - Description.
  - Intended of use.
  - Formula and/or composition. (if applicable)
  - Stability. (if applicable)
  - Sterility. (if applicable)
  - Primary and Secondary packaging information

Registered Certification Entity

Certification Number
• **Certification** issued by the Registered Certification Entity:

<table>
<thead>
<tr>
<th>Certification No.</th>
<th>Solicitud Referencia</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Note: Authenticated (Apostille)
• **Export Notification** with the following specifications:

- Description.
- Intended of use.
- Presentations with codes (catalog number, part number, etc.) including accessories.
- Formula and/or composition.
- Stability. (if applicable)
- Sterility Period (if applicable)
- Primary and Secondary packaging information.

Seal by the Ministry of Health of Japan
Brand Name of the Medical Device

Codes of the presentations of the product

Authenticated (Apostille)

Note: Legal translation
• Original or Certified Copy of the **Free Sales Certificate**
  *No older than one year.*

Issued by the Ministry of Health of Japan

No older than one year

Medical Device Data
Authenticated (Apostille)

MINISTRY OF HEALTH, LABOUR AND WELFARE
GOVERNMENT OF JAPAN
2-5, SARUMIGASEKI 1-CHOME, CHIYODA-KU, TOKYO 100-8916

CERTIFICATE

APOSTILLE

1. Country: JAPAN
   This public document has been signed by
2. acting in the capacity of
3. bears the seal/stamp of
4. Certified
5. at Osaka
6.
7. by the Ministry of Foreign Affairs
8. No.
9. Seal/Stamp:
10. Signature:

Note: Legal Translation.
Designated Controlled Medical Devices (Class II in accordance with criteria established) with Certificate Issued by a Registered Certification Entity before the MHLW in Japan (COFEPRIS-04-001-G)
• **Approval Letter** e issued by the MHLW of Japan, including the sheets where the following topics are specified:

- Description.
- Intended of use.
- Formula and/or composition. (if applicable)
- Stability. (if applicable)
- Sterility. (if applicable)
- Primary and Secondary packaging information

Seal by the Ministry of Health of Japan
<table>
<thead>
<tr>
<th>Brand Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>Manufacturer Data</td>
</tr>
</tbody>
</table>

Seal by the Ministry of Health of Japan

Authenticated (Apostille)
• **Export Notification with the following specifications:**

- Description.
- Intended of use.
- Presentations with codes (catalog number, part number, etc.) including accessories.
- Formula and/or composition.
- Stability (if applicable)
- Sterility Period (if applicable)
- Primary and Secondary packaging information.
Brand Name of the Medical Device

Codes of the presentations of the product

Authenticated (Apostille)

Note: Legal translation
• Original or Certified Copy of the **Free Sales Certificate**
  No older than one year.

Issued by the Ministry of Health of Japan

Medical Device Data

No older than one year
MINISTRY OF HEALTH, LABOUR AND WELFARE
GOVERNMENT OF JAPAN
2-3, SARUMIGASKI 1-CHOME, CHIYODA-KU, TOKYO 100-8916

CERTIFICATE
(Convention de La Haye du 5 octobre 1961)

1. Country: JAPAN
   This public document
2. has been signed by
3. acting in the capacity of
4. bears the seal/stamp of

Certified or

5. at Osaka
6. 
7. by the Ministry of Foreign Affairs
8. No. 
9. Seal/Stamp: 

10. Signature: 

000146

Note: Legal Translation.
Class II Medical Devices (class II without criteria established in accordance), III and IV with Approval Letter Issued by the MHLW in Japan (COFEPRIS-04-001-H).
Agreement for Low Risk Medical Devices
CLASS IA SANITARY LOW RISK AND EXEMPT

• There is an Agreement that is given to know the list of health products considered at low risk for purposes of obtaining an Approval, and products that by their nature, characteristics and use are not considered devices for the health and therefore do not require authorization.

• Published in the Official Gazette on December 31, 2011
CLASS IA SANITARY LOW RISK AND EXEMPT

- All devices that are now considered as low risk, have 5 years from the publication of the agreement to perform the procedure. (Appendix One)
- For those that are Exempts of an Approval the Ministry of Health will issued an Official Document of Exempt, this document don´t have an expiration date, however it can be updated if user require it. (Appendix Two)
- COFEPRIS is working with several Mexican Chambers (CANIFARMA, AMID, CANACITTRA, AMIC, etc) in order to update both Appendix.
Requirements for the Approval
Of MEDICAL DEVICES Import Products (Foreign Manufacture) Consider Low Risk

Requirements

1. Registration Application Form
2. Proof of Payment of fees Class IA
3. Notice of Retail Operation in Mexico and Notice of Health Responsible
4. Project Tag according to the established in the NOM-137-SSA1-2008, “Labeling Medical Devices”
5. Letter of Representation issued by the Manufacturer
THANKS