Important points to consider before entering the Chinese Medical Device Market
Specific to Medical Devices, CFDA, the Chinese Food and Drug Regulatory agency, is revising and improving many of its existing regulations for marketing approvals for commercial sale within China.

For Overseas Medical Device Manufacturers, who wish to register their products in China should thoroughly understand the process and plan much before starting such processes, because although it is a lucrative market it still employs a comprehensive and lengthy process which might seem formidable for the first time entrants.

The basic outline of the registration process for all overseas medical device manufacturers is as follows:

- All Class I devices should be filled with the CFDA before starting the commercial distribution in the country.

- All Class II and Class III devices require comprehensive registration of product with the CFDA, and require approval before local sales.
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The Figure is only an indicative illustration of the process for Medical Device registration with CFDA.

But Following are some of the important aspects that should be considered while planning the regulatory strategy for China:

**Information:**
The available information from CFDA is very limited in the English Language, however very thorough information is available in the Chinese language. So do not consider the documents available in English as requirements limited to.

**Classification:**
It is not quite obvious to clearly understand the classification of your product, so instead of assumptions make sure to consult a local consultant or CFDA, because the process, timeline and very soon the Fees could vary significantly, leading to huge delays and possibility of loss of fees.

**Testing: (Type Testing) and Standards**
Most of the devices require testing at the local labs, approved by the government. However the test methodologies and parameters are to be provided by the manufacturer, so it is very important to take the help of local experts, to determine and develop protocols for testing by the labs, who understand the type of test data that CFDA would like to see, from these tests conducted by the local labs.

**Biocompatibility:**
The globally accepted materials as biocompatible may not have the same influence on the CFDA reviewers, even if a lot of publication data is available. Understand the requirements from the materials perspectives well.
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Language of Communication:
All applications and data to be submitted in Chinese language, and should be accompanied with the text in the original language from the country of origin. Lot of translation is required, but important to note is the care that needs to be taken while translating technical data. So it is important to engage experts who understand the products and processes from the technical perspectives when it comes to explaining your product and data to CFDA in Chinese language. Obvious is to engage good engineers, would help you to overcome the language barrier.

Recently new regulations released:
The regulations for registration of Medical Devices and In-vitro diagnostics have been revised, so make sure that the latest documents are being referred. Again, more information is available in Chinese language so it is important to know every requirement, before moving forward. The overall requirements may not look much different however the data requirements have been revised at the granular levels.

Clinical Data:
Submission of data from the country of origin is very important. CFDA has also released the categories of devices for which local clinical trial data is must and have excluded some devices from the mandatory local clinical data requirements both in Class II and Class III segments. Any clinical trials conducted locally are to be conducted at government approved Sites only.

Length of Approval:
The length of the total project and approval still takes on average a little above 2 years.

Last But the most important; Change in User Fees:
There User fees for Medical Devices and IVDs is going to change very soon and is going to increase. CFDA proposed the following fee structure for all Overseas Medical Device Manufactures:

<table>
<thead>
<tr>
<th>Product Class</th>
<th>Application Type</th>
<th>Approx. Fees in USD as original cost is in RMB</th>
</tr>
</thead>
<tbody>
<tr>
<td>Class II</td>
<td>Initial registration</td>
<td>35000</td>
</tr>
<tr>
<td></td>
<td>Change application</td>
<td>7000</td>
</tr>
<tr>
<td></td>
<td>Extension application</td>
<td>6500</td>
</tr>
<tr>
<td>Class III</td>
<td>Initial registration</td>
<td>50000</td>
</tr>
<tr>
<td></td>
<td>Change application</td>
<td>8200</td>
</tr>
<tr>
<td></td>
<td>Extension application</td>
<td>6500</td>
</tr>
</tbody>
</table>
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The proposed regulation of the new user fee is not yet applicable, but from the local intelligence is expected to come in force from March 2015.

**Overall:**

While China is a very important market, it is must to have lot of planning before approaching the market, starting from Market feasibility, Product classification, Type Testing strategy, Clinical data requirements, Timelines and overall costs (Translation costs, lab testing, clinical trials, New CFDA User fee, consulting fees, etc.. in all will be a significant investment).