CASE STUDY

PharmaLex obtains rapid CE marking for a medical device that opens up a market worth $2.2 billion

Situation

A US-based company had developed a Class III medical device for the treatment of hepatic cancer. The device had been designed to be used with a specific medicinal product. The company wanted to sell their product in the EU and the product must therefore carry a CE mark.

Challenge

To obtain a medical device CE mark, the manufacturer must submit a dossier of scientific and technical data to a Notified Body for assessment. They must also have a compliant Quality Management System (QMS).

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Solution

Using our significant medical devices expertise and great commercial awareness, PharmaLex proposed to the client that their device be CE marked for use with chemotherapeutic agents in general rather than just the one the company had proposed.

- PharmaLex liaised with the Notified Body to gain a CE mark with a broad use
- PharmaLex helped the company generate and submit the correct information to get their CE mark application right first time
- PharmaLex supported the company to implement a compliant QMS
- PharmaLex gained approval for the company's product in a short time.

Benefits

The PharmaLex engagement delivered:

EU sales of the produact worth £2M in Year 1

Access to a market worth $2.2B.

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