## Case Study 2: Product Code selection is Key

We at Compliance Insight worked with a small Korean medical device company that encountered significant delays due to an early strategic mistake.

They developed a low-powered electrosurgical cutting device and, based on their internal research, selected product code GEI—an older, broad category for electrosurgical devices—and chose two predicates they believed would cover their device's features.

Unfortunately, they misunderstood how to properly match a predicate device to their specific technological characteristics and intended indication for use. Even though they selected the current product code, their performance testing was based on a predicate that the FDA later deemed inappropriate for their device.

This misstep created a major problem during the FDA's review. The FDA determined that their device did not belong under product code GEI at all and instead required reclassification under a newly established product code specifically for lower-powered electrosurgical cutting devices. That meant the Korean company had to switch product codes mid-submission, select a different predicate device under the new code, and submit a completely new comparison table—costing them valuable time and effort.

Fortunately, Compliance Insight was there to guide them. We stepped in, helped the company realign its strategy, supported the generation of the necessary performance data, and ensured everything matched FDA expectations.

Thanks to this course correction, the company's device was successfully cleared and is now available in the U.S. market.

***Key Takeaway***: It's not enough to pick a product code—you must also select the right predicate and understand the FDA's expectations around performance comparisons. Working with an experienced partner from the start can prevent these costly missteps.

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