Determining When a Device is 510(k) Exempt

The first step is to classify the device using the information on the FDA website. One method uses the Product Classification search engine:
http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpcd/classification.cfm

The Product Code information on the FDA website identifies the relevant characteristic, including whether the device is 510(k) exempt. Remember that the class does not determine the need for a 510(k). (The infant heel warmer, Product Code MPO, is a Class 1 device that requires a 510(k) based on the intended use, not the class.)

The regulations provide additional information. In general, xxx.9 provides limitations that the manufacturer must take into account.

There are Warning Letters that identify cases in which the manufacturer exceeds the xxx.9 limitations. Often, the Warning Letters cite problems in intended use as inferred from marketing claims. To see an example, read the November 19, 2015 Warning Letter to A-1 Engineering. I've cited two relevant paragraphs, which are "stock" elements in this kind of Warning Letter.

"Because there is evidence that the Neurotris SX-Series machines and PICO Toner are intended for uses that are different from those of legally marketed devices classified under 21 CFR §890.5660, they exceed the limitations described in 21 CFR §890.9(a) and are not exempt from premarket notification."

"Our office requests that A-1 Engineering immediately cease activities that result in the misbranding or adulteration of the Neurotris SX-Series Machines and PICO Toner, such as the commercial distribution of the devices for the uses discussed above."

For the manufacturer, there are a few issues to consider. First, this is an opinion offered at a point in time. If the manufacturer's marketing department wishes to later make claims outside the initial intended use, then that would negate the initial analysis.

In preparing an analysis, include a few basic elements.

Cite the Product Code and all the information from the classification page. A screen shot showing the date is best, because FDA could make changes later.

Cite the regulation and all of the relevant sections. Include the FR citation to help identify the version cited. (Unlike other documents, the Federal Regulations don't have a version number.)

Obtain a copy of the intended use statement. It should be under document control and readably accessible. Cite the version including the document number and revision. Remember that during the design phase, the design project could use an informal document control system. For most Class 1 devices, design control doesn't apply. In any case, include the full statement of the manufacturer's intended use.

Review the xxx.9 section of the regulation. Make a table of the limitations in one column, in the next column a statement of whether or not the intended use satisfies the limitations, and in the last column the rationale for your conclusion, citing the specifics of the intended use statement.