Classification

The MHRA consultation document issued late 2021 recognised that existing classification rules in the UK are, in some cases, not in line with best International practices. The MHRA stated their belief that there is a need for these rules to be amended in order to keep pace with technological and medical progress.

We continue our series of summarised elements from the aforementioned publication with a look at stated intentions in the important area of device Classification which dictates the level of regulation that covers particular devices.

The Government in their response to the feedback received has indicated that it is in favour of progressing all classification changes proposed in the consultation document which include:

- Surgical meshes could be moved to the highest risk category (Class III).
- Joint replacements (total or partial) could be moved to the highest risk category (Class III).
- New classification rules to be introduced for software as a medical device (SaMD) which align with the IMDRF guidance on software classification. These classification rules consider the state of the patient's healthcare condition and how the software is being used.
- A definition for "Software" will be added to the UK medical device regulations as "*A set of instructions that processes input data and creates output data"*.
- New classification rules to be introduced for IVDs – The intention is to move away from the current list based approach to a risk based approach similar to what has happened with the new EU regulations. This would likely see an increase in the proportion of IVDs that are in higher risk classes, increasing the level of scrutiny applied to IVDs.

The need for good guidance around classification and the changes was also recognised in the Government response and they state they will ensure it is available.

Whilst the Government is in favour of these changes they also state that they are subject to the following:

a. the amendments it is considering around the classification of IVF/ART related devices would apply specifically to substance-based devices used in vitro in direct contact with human embryos before implantation or administration into the body, and not to every tool used in IVF/ART. We consider that up-classification is warranted for these limited devices involved in IVF/ART to ensure that the classification risk is commensurate with the risk that such a device presents, but not for all devices involved in these procedures, the majority of which are classified appropriately by existing classification rules, and
b. the amendment to the classification of medical devices incorporating nanomaterials (being classified between Class IIa – III depending on potential internal exposure levels) should apply not only to those incorporating nanomaterials, but also to those generating nanomaterials.