

## Case Study 69:

### Registration of Special 510(K) for Medical Gloves with FDA -USA



#### Client

US Medical Device company that manufactures and sales Gloves for Examination in USA, wanted to commercialize a new model of their Gloves with a different color and was seeking support to register this new model with FDA.

#### Products

No-Sterile, Powder-free Nitrile Exam Gloves.

#### Product Categories

Examination Glove , Class I medical device

#### Countries of Interest

USA

#### Solution Offered

- ✓ US Agent
- ✓ RA strategy
- ✓ Special 510(K) preparation and submission to FDA

#### Key Highlights:

- ✓ GRP's team brings decades of experience from medical device industry requirements and has helped over 50 manufacturers to register their medical devices with FDA.
- ✓ Because of the Regulatory strategy proposed to the client and quality of special 510(K) that was prepared and submitted to FDA by GRP, the new model of Gloves were approved ( cleared) by FDA in 30 days and the client was able to commercialize them in US market in record time.

#### Keywords:

Special 510(K) clearance FDA, RA strategy FDA, medical Gloves registration FDA, 30 days clearance gloves new color FDA, Non-sterile powder nitril gloves approval FDA

#### Client Situation

US Medical Device company that manufactures and sales No-Sterile, Blue Powder-free Nitrile Exam Gloves that are used for medical examination, wanted to commercialize in USA a new model of same gloves with a different color (purple), and was looking for regulatory affairs professional who can give them guidance on how to register the new model with FDA.

#### GRP Solution

GRP Regulatory Affair team in USA helped many American and foreign medical device companies register their PPE with FDA, including different categories of medical Gloves during Covid-19 pandemic. After receiving a copy of the original (traditional) 510(K) from the client, GRP performed:

- ✓ A GAP analysis and established RA strategy for the registration of new model of Gloves with FDA.
- ✓ Conducted the substantial equivalence analysis and concluded that no additional performance studies will be required for the new gloves' registration with FDA
- ✓ Conducted the biocompatibility analysis and wrote the rational that no additional biocompatibility studies will be required for the new model of Gloves
- ✓ Prepared and submitted a special 510(k) for the new model of gloves.
- ✓ Received the clearance for the special 510(k) in 30 days from FDA.



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