Approval Date: August 27, 2020

Product: AFLURIA

Proper Name: Influenza Vaccine

Manufacturer: Seqirus Pty. Ltd.

Indication: For active immunization against influenza disease caused by influenza virus subtypes A and type B present in the vaccine.

Description: AFLURIA, Influenza Vaccine for intramuscular injection, is a sterile, clear, colorless to slightly opalescent suspension with some sediment that resuspends upon shaking to form a homogeneous suspension.

BLA: BL 125254

Regulatory Milestone:

CDRH cleared the 510(k) Stratis device application on July 27, 2011 based on the determination that it was substantially equivalent to the predicate device: PharmaJet 0.5 ml Needle-Free Injection System (K081632). In October 2011, FDA issued a communication stating that influenza vaccines should be administered by needle and syringe only.

PDUFA Goal Date: August 22, 2014

Package Insert: Package Insert - AFLURIA

Summary Basis for Regulatory Approval: August 15, 2014 Summary Basis for Regulatory Action - Afluria

European Public Assessment Report: No data

Advisory Committee:

A Vaccines and Related Biological Products Advisory Committee meeting was not convened because the review team did not identify any safety or immunogenicity issues necessitating an advisory committee discussion.

Safety:

Safety was acceptable although local reactogenicity was significantly greater in the Stratis device group. Notably, subjects in the Stratis device group were approximately 10 times more likely to state that they would not choose to receive immunization by jet injector again. The greater local reactogenicity associated with administration of Afluria by the Stratis device was expected based on previous clinical studies of immunization by jet injectors. Overall, and despite the results of the immunization experience questionnaire, the safety profile of Afluria administrated by the Stratis device was acceptable. No new concerns about the safety of Afluria were raised in this study independent of the method of administration.

NCT Numbers:

- NCT03442582
- NCT00735475
- NCT01591837
- NCT03056924
- NCT01825200
- NCT01857297
- NCT02947217
- NCT00902278
- NCT01688921
- NCT00959049
- NCT02946177
- NCT01248208

EudraCT Numbers:

- 2014-004131-40
- 2015-000175-27
- 2014-003768-19

- 2016-004753-33
- 2016-004133-25

Publications:

- Couch, R. B., Atmar, R. L., Keitel, W. A., Quarles, J. M., Wells, J., Arden, N., & Niño, D. (2012). Randomized comparative study of the serum antihemagglutinin and antineuraminidase antibody responses to six licensed trivalent influenza vaccines. *Vaccine*, *31*(1), 190–195. https://doi.org/10.1016/j.vaccine.2012.10.065
- Treanor, J. T., Albano, F. R., Sawlwin, D. C., Graves Jones, A., Airey, J., Formica, N., Matassa, V., & Leong, J. (2017). Immunogenicity and safety of a quadrivalent inactivated influenza vaccine compared with two trivalent inactivated influenza vaccines containing alternate B strains in adults: A phase 3, randomized noninferiority study. *Vaccine*, *35*(15), 1856–1864. https://doi.org/10.1016/j.vaccine.2017.02.066
- Statler, V. A., Albano, F. R., Airey, J., Sawlwin, D. C., Graves Jones, A., Matassa, V., Heijnen, E., Edelman, J., & Marshall, G. S. (2019). Immunogenicity and safety of a quadrivalent inactivated influenza vaccine in children 6-59 months of age: A phase 3, randomized, noninferiority study. *Vaccine*, *37*(2), 343–351. https://doi.org/10.1016/j.vaccine.2018.07.036
- Forster, A. H., Witham, K., Depelsenaire, A., Veitch, M., Wells, J. W., Wheatley, A., Pryor, M., Lickliter, J. D., Francis, B., Rockman, S., Bodle, J., Treasure, P., Hickling, J., & Fernando, G. (2020). Safety, tolerability, and immunogenicity of influenza vaccination with a high-density microarray patch: Results from a randomized, controlled phase I clinical trial. *PLoS medicine*, *17*(3), e1003024. https://doi.org/10.1371/journal.pmed.1003024