

K203276 Bead Block (100 - 300µm, 1ml), Bead Block (300 - 500µm, 1ml), Bead Block (500 - 700µm, 1ml), Bead Block (700 - 900µm, 1ml), Bead Block (900 - 1200µm, 1ml), Bead Block (100 - 300µm, 2ml), Bead Block (300 - 500µm, 2ml), Bead Block (500 - 700µm, 2ml), Bead Block (700 - 900µm, 2ml), Bead Block (900 - 1200µm, 2ml)

Apr 20, 2021
165 days to decision

K203276 · Product code: **NOY** · Neurology
Source: <https://www.510kdatabase.net/k203276/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Agents, Embolic, For Treatment Of Benign Prostatic Hyperplasia (NOY)
Date received	Nov 6, 2020
Decision date	Apr 20, 2021
Days to decision	165 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Biocompatibles UK Ltd (Part of Boston Scientific Corporation)
Location	Farnham, GB
Contact	Christina Fischer
510(k) history	1 submissions · 1 cleared · 2021-2021

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k203276/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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