Application for granting a new RoHS exemption:

Leaded solder utilized in stacked, area array electronics packaging within ionizing radiation detectors including CT and X-ray

Name and address of applicant

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1. Summary of the application

A new digital X-ray detector architecture is being developed that will allow patients to be exposed to lower X-ray doses but this design requires the use of a solder alloy containing lead. This exemption is required because the interconnects within these architectures require a lower temperature solder with superior wetting and reflow that is compatible with the stacked assembly requirements and the only viable solution found has been eutectic Pb/Sn solder. Research has been carried out with a SAC solder but this gives unsatisfactory performance and no other lead –free solder has all of the essential requirements. All alternative design of digital silicon X-ray detector require higher X-ray doses to the patient which have been shown to increase the risk of side-effects such as cancer.

2. Description of materials and equipment for which the exemption is required

Detectors have evolved from a distributed or remote assembly technique where flex circuits were used to transport low level analogue signals to remote electronics found on the perimeter of the system. This architecture was sufficient when performance, coverage and total number of pixels were lower than is required today. However, current state of the art detectors are increasing in dose efficiency requiring lower electronic noise levels as well as increasing total size and coverage, pushing the size of detectors to increase. Larger detectors are needed to allow imaging of organs such as the Liver or Heart in a single exposure and for single tomographic rotation providing better temporal resolution and a reduced overall patient dose. Lower X-ray dose equates to less X-Ray reaching the detector requiring improved analogue performance of the detector system including the electrical interconnections. Furthermore, improved temporal resolution requires that fewer detector sensor elements share the same analogue-digital conversion channel. By locating electronics closer to the X-Ray scintillator and photo diode assembly the analogue path is as short as possible and significantly improves the system’s electrical performance. This assembly method increases the signal to noise ratio so that the minimum signal required for good images can be achieved using a lower radiation dose. Reducing the analogue path requires stacking electronics on a large area array, which includes the scintillator and diode assembly. To manufacture stacked large area arrays with over 500 interconnects requires multiple assembly process steps and lower solder reflow temperatures with subsequent soldering steps. The first soldering step uses tin/silver/copper (SAC) solder that melts at ~220°C followed by soldering with eutectic tin/lead (SnPb) solder that melts at 183°C. The use of a leaded solder interconnect step is a requirement that has been demonstrated to be necessary for successful manufacture and design robustness.

The number of area arrays used for one detector varies depending on the detector size and shape but can have over 100,000 solder bump connections. One defective bond can appear as a feature in images causing possible misdiagnosis and so being able to achieve 100% perfect bonding and extremely high reliability are essential to avoid such problems.

This design of detector for ionising radiation is constructed as follows: In the assembly of an ionizing radiation detector, multiple stacked die elements (SDE) are arrayed in two dimensions forming the overall detection area. SDE's enable the detector to be assembled on a flat plane for standard projection X-ray imaging, or in a curved shape for use in computed tomographic (rotating) systems.

An electrical connection must be made at progressively independent times during the manufacturing process. Assembly of the SDE relies on multiple and different solder reflow temperatures found in various levels of the assembly. The first solder bonds are made with SAC305 as a higher temperature than the tin/lead solder bond between the PTC and 2SP BGA devices.

The lead-free solder alloy SAC305 (95.5%Sn, 3.0% Ag, 0.5%Cu) has a melting point of ~220 °C. Standard eutectic (melting at a single temperature) tin-lead solder (63% Sn, 37% Pb) has a melting point of 183 °C. The use of the lower soldering temperature of SnPb avoids re-melting or part melting the previously formed SAC305 solder bonds which would increase intermetallic thickness (this forms most rapidly when the solder is molten) which would increase the risk of fatigue failure. Research has demonstrated that it is necessary to use the SnPb solder across the large analogue area array because of its lower melting temp of 183°C, its eutectic behaviour with a single melting point (i.e. no pasty range) and has superior ductility compared with most lead-free solders. A higher solder reflow temperature across a wider span would require a tighter matching of component CTE (Coefficients of Thermal Expansion) in the assembly but this is not feasible with this design due to the requirements of the individual components. The PTC must match the very low CTE of the silicon photodiode because the photodiode is extremely fragile. The 2SP devices are commercial BGAs which polymer laminate layers as the internal interconnect which will have a much higher CTE than the PTC. The 2SP device is not available with ceramic interconnects as the polymer laminate is needed to achieve the high interconnect density that would not be achievable with ceramic circuits. Utilizing the lower temperature of SnPb at the area interconnect has been found to greatly improve the manufacturability and reliability, especially in the outer region of the large analogue array where stresses due to the TCE mismatch are the greatest.

3. Justification for exemption – Article 5 criteria

The stacked assembly process with large area array interconnects is a unique design which is needed for wide coverage X-ray and CT detectors that would allow lower X-ray doses to be given to patients. Wide coverage is attained by arraying the SDEs which improves the temporal response of the system providing for current and future low dose, high resolution clinical needs. The density and variety of stacked materials that are used, associated with the coefficients of thermal expansion required in the detector element creates a specific combination of essential requirements for the interconnection materials for which only tin/lead solder has been found to be suitable. The lower melting point eutectic, ductile nature of leaded solder (SnPb) is needed to achieve an assembled product that can be manufactured with high yield and is a reliable product. This exemption is required because the interconnects within these architectures require lower temperature solder with superior wetting and reflow and good ductility that is compatible with the stacked assembly requirements and the only viable solution that has been found is eutectic Pb/Sn solder. Therefore this is exemption is justified as no scientific or technical substitute without lead is available.

4. Analysis of possible alternatives

Due to the constraints of the complex array of parts and materials used, the only potential substitute to SnPb solder would be alternative solders. The most commonly used lead-free solder used for electrical equipment is the SAC alloys and so SAC 305 was selected for comparison with SnPb solder.

Alternative designs have been considered but have unresolved technical disadvantages due to the large area array and CTE (Coefficient of Thermal Expansion) mismatch of materials in the stacked assembly.

During the development of the assembly process, many manufacturing lots using 6 Sigma methods known as DOEs (design of experiments) were completed with greater than 100 parts constructed with SAC 305 solder. Careful adjustments to solder printing stencil aperture size, solder volume, reflow thermal profiles (ramp up and down) etc. were attempted to determine the quality and performance of the solder bonds. However, numerous solder interconnect failures were documented through careful failure analysis techniques such as "dye and pry"[1] and detailed solder joint and pad micro sections. A quality analogue interconnect array could not be produced after extensive trials during an ~18 month time frame and significant resource investment where all variables were investigated.

By contrast, SDE's were constructed in which the analogue interconnect array was created using eutectic Sn-Pb solder. The same Dye & Pry analysis was performed which is showed excellent connections.

[1] "Dye & pry" is where a highly penetrative dye solution is injected around the solder bonds and allowed to penetrate into any cracks that are present. The dye is then dried before the solder bonds are broken by prizing apart that BGAs from the PTC. The presence of red dye on the fracture surface confirms that cracks were present.

Another difficulty in this type of stack die assembly is the variation in adjacent solder joint height that may be required. Again, eutectic tin-lead solders were found to provide the best overall solder quality including column geometry when challenged with this type of adjacent solder joint height variation.

Assembly of SDEs was attempted using SAC305 solder throughout but results were extremely poor. Cracks in the solder bonds of the analogue array interconnect defects within a single element were found. Therefore accelerated stress testing has not performed because lead-free analogue interconnect array baseline units could not be produced without defects. Detector imaging system assemblies require as many as 400 or more of these SDE's but a single interconnect failure may result in image artifacts and overall system malfunction and image integrity so is not acceptable. A concern is that if defect free assemblies could be produced with SAC, the rigidity of the solder and the large TCE mismatch is more likely to cause fatigue failure than SnPb solder.

Other solders.
There are many other lead-free solders available but these have not yet been tested. However, it is not expected that any of these will give the same performance as eutectic SnPb solder because none have the required combination of properties as summarised below:

Solder alloy	Melting temperature	Characteristics[2]
SnPb	183 °C	Ductile and has m.pt. ~35°C lower than SAC
SnCu	227°C	Higher m.pt. than SAC, not ductile
SnAg	221°C (3.5%Ag)	Slightly higher m.pt. than SAC. Not ductile
Sn3.5Ag0.5Cu	217 °C	All SAC alloys are much harder than SnPb: SAC Vickers hardness = ~21 whereas SnPb hardness = 12.9
Sn-3.5Ag-3Bi	206 – 213°C	Fully melts at only 4°C below SAC 305's m.pt. Bismuth addition increases hardness and so reduces ductility
Sn3Ag3Zn	Not available	Vickers hardness about double that of SnPb (21.9). Alloys with zinc suffer from corrosion so are unsuitable for products with long lifetimes.
Sn3Ag3In	Not available	Vickers hardness about double that of SnPb (21.3)
Sn9Zn, Sn8Zn3Bi	189 - 199	The zinc content makes this alloy very susceptible to corrosion. Sn8Zn3Bi is not ductile due to bismuth content (Vickers hardness = at least 23)[3].

[2] Some solder hardness data is from table 2.2.15 of http://swp.fr/metaconcept-v1/telechargement/notes/Liste_dalliages_sans_plomb_ANG.pdf
[3] http://www.jim.or.jp/journal/e/pdf3/43/08/1797.pdf

Sn20In2.8Ag	175 - 187	Availability of indium is an issue. This alloy is expensive due to the high indium content and so is rarely used and very little reliability data published. It is also susceptible to corrosion under high humidity conditions. A low melting temperature phase with m.pt of 118°C[4] has been detected which will limit operating temperature which must be well below this temperature. No hardness data published.
58Bi42Sn	138	Very hard alloy due to high bismuth content. Research also shows that this is more susceptible to thermal fatigue than SnPb[5]

There are a few lead-free solder alloys with melting points lower than SAC305 which are sufficiently lower to prevent the SAC305 bonds from melting when the PTC - 2SP bonds are formed. These alloys include Sn9Zn, Sn8Zn3Bi and Sn20In2.8Ag. These alloys however have a ~10°C melting range, as they are not eutectic alloys which as explained above, is a requirement. The SnZn alloys are also harder and less ductile than SnPb and both these and Sn20In2.8 are susceptible to corrosion and so would not be suitable in medical devices that have long service lives. The BiSn solder is also not sufficiently ductile for this application.

Another potential substitution option would be to use SAC305 instead of SnPb and a higher melting point solder to make the first solder bonds. There are two reasons why this would not be possible:

- SAC305 is much less ductile than SnPb so the PTC-2SP bonds are likely to fracture during assembly as shown in figure 3.
- Lead-free solders with melting point ~30°C higher than SAC305 need to melt at 247°C or higher. There are very few choices of which Sn5%Sb, m.pt 232 - 240°C has too small a difference (only 12°C) and all other choices, such as AuSn have a m.pt (280°C) which are too high as this temperature will destroy some of the materials used for the assembly such as the flex circuit.

Alternative designs.

This new technology is being developed to replace existing designs of silicon X-ray detector to obtain several advantages that cannot be achieved with current designs. This technology will provide larger area detectors and lower radiation doses. Being able to see a larger area gives superior diagnostic capability which will improve human health. As explained in section 2, imaging the whole liver or heart in one image has several advantages which assist with diagnosis. It is often necessary to view a large area simultaneously such as the head / neck and this requires quite large detector areas that are difficult to achieve with silicon detectors. Therefore limiting detector size to smaller areas could result in a negative impact on human health.

[4] See page 20 of http://www.colorado.edu/engineering/MCEN/MCEN5166/Homeworks/chapter_solder_opkg.PDF

[5] HP tested 58%BiSn with 63%SnPb for cyclic thermal fatigue resistance and found that SnBi bonds failed much sooner than SnPb with all of the package types tested. “Low-Temperature Solders”, Z. Mei, H. Holder and H A. Vander Plas. H. P Journal, August 1996.

This new design, as explained in section 2, has the advantage that the low level analogue circuit paths are shortened. Shortening these signal paths and utilizing state of the art ASIC design techniques minimizes the electronic noise in the data acquisition system. When the number of photons from an X-Ray beam are reduced to the level where the detected signal is as small as signal from electronic noise in the acquisition system, the images will have significantly degraded image quality. Therefore, it is desired to reduce the electronic noise in order to improve image quality in low dose examinations. Low dose examinations are typically seen when large patients block the X-Ray beam. In this application a reduction in e-noise improves the SNR by approximately 30% which leads to approximately 20% to 25% reduction in dose. Research into the effect of radiation dose has shown that there is a linear relationship between radiation dose and risk of cancer. The International Commission on Radiological Protection (ICRP)[6] has determined that the risk coefficient is 5% at 1 Sievert although this is a very high dose and low mS doses are more typical of medical imaging. One of the highest X-ray doses used for imaging is used for cardiology where continuous irradiation is needed to view blood vessels during surgical procedures. Huda[7] has established that typical CT doses which are similar to cardiology doses cause about 1 person in 1,000 (0.12%) to have cancer. In this case, a 10% increase in radiation dose will cause statistically one additional person in 10,000 to have cancer. Clearly, it is important to minimise radiation doses and the "Directive 97/43/Euratom – Medical Exposures Directive" requires that all patient exposures are optimised and so if RoHS were to result in doses that were higher than could be achieved, this would conflict with this directive.

5. Life cycle comparison of alternative options

The two options are solder with lead or solder with silver. Full life cycle assessments have been carried out by the US Environmental Protection Agency (EPA)[8] who compared SnPb with SAC as well as other solder compositions. This concluded that for the majority of environmental impacts, lead-free solders had greater negative impacts than the tin/lead solder they replace.

Extraction, refining and production

The US EPA study showed that SAC solder paste reflow consumes slightly more energy than all of the other solders and the main reason is energy for extraction and refining of silver and the higher melting temperature than SnPb. The US EPA study gave environmental impact scores for energy use for the paste solders:

Alloy	**10^4 MJ energy / dm^3 solder**
SnPb	1.25
SAC (Sn3.9Ag0.6Cu)	1.36
SABC (Sn2.5Ag1Bi0.5Cu)	1.31

[6] ICRP publication 103 "The 2007 Recommendations of the International Commission on Radiological Protection.
[7] W. Huda, W. T. Rowlett and U. J. Schoef "Radiation dose at cardiac computed tomography: facts and fiction" J. Thorac. Imaging, 2010 Aug; 25(3) p 2014
[8] http://www.epa.gov/dfe/pubs/solder/lca/index.htm

EPA's results for the low melting point bismuth tin silver alloy are excluded here as this solder cannot be used for PET/MRI PCBs due to its too low melting temperature as it cannot be used with BGAs having SAC or SnPb balls.

Extraction and refining of silver creates significantly more waste than lead and so SAC and SABC have significantly larger environmental impacts

Alloy	dm^3 waste created / dm^3 solder
SnPb	2.75
SAC	16.2
SABC	11.3

SnPb solder had a greater impact than SAC and SABC for occupational health and public health –non cancer but SAC had the largest public health-cancer impact. Overall SnPb had the largest impact for six impact categories whereas SAC had the largest impact for 10 categories. The US EPA stated that different environmental impacts cannot be compared but since the LCA was published, research has been carried out to determine how they can be compared (e.g. by assessing weighting factors for each impact) but this work is not yet complete.

Use phase

The choice of solder alloy has no impact on the use phase as long as it does not affect reliability. If an alloy were to be less reliable causing unexpected early failures, this would potentially have a serious impact on patient health and would create additional waste.

Re-use and recycling of materials from waste EEE.

When X-Ray and CT Detectors reach end of life the parts are separated and recycled or may be re-used in refurbished units. The separated parts are mostly aluminium which is recycled as metal with very high yields. The mass of output of Lead (Pb) expected in the SDE is extremely small and is safely treated as hazardous waste.

6. Other information

The total amount of Lead (Pb) that would be shipped to the EU in ionizing radiation detectors is expected to reach 1.2 Kg annually. The amount used globally is predicted to reach 4.55 kg per year

7. Proposed plan to develop substitutes and timetable

We are aggressively assessing the use of various ASIC packaging techniques to better match TCE of the Diode. We expect this to be accomplished within five years by 2017.

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The first phase of development will require the identification of a lead-free solder that is relatively ductile, is a eutectic alloy and has a melting point at least 20°C lower than the lead-free solder used for the previous soldering step. If this proves to be impossible then the only option is alternative design architectures and at present no suitable designs are known. The following timescale may be achievable if a suitable alloy can be found or an architecture can be developed.

Basic Timing:

Research Phase: already started, expected to take until ~2014
This will include testing of solders and investigation of alternative interconnection architectures involving various area array technologies.

Development Phase: during 2015-2017
Specific component design, mass production process designs and robust reliability testing including G force and thermal cycle stress testing.

Construction and reliability testing of imaging equipment: takes ~ 2 years, from 2017 - 2019

Approval by Medical Devices Directive: can take up to 1 year, therefore to 2020

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8. Proposed wording for exemption

Leaded solder used to create stacked, area array electronics within ionizing radiation detectors used in CT and X-ray systems until 31 December 2019 and in spare parts for CT and X-ray systems placed on the EU market before 1 Jan 2020.